S. Hrg. 98-1060

NATIONAL CHILDHOOD VACCINE-INJURY COMPENSATION ACT

HEARING

BEFORE THE

COMMITTEE ON
LABOR AND HUMAN RESOURCES
UNITED STATES SENATE

NINETY-EIGHTH CONGRESS

SECOND SESSION

ON

S. 2117

TO AMEND THE PUBLIC HEALTH SERVICE ACT TO PROVIDE FOR THE COMPENSATION OF CHILDREN AND OTHERS WHO HAVE SUSTAINED VACCINE-RELATED INJURY, AND FOR OTHER PURPOSES

MAY 3, 1984

Printed for the use of the Committee on Labor and Human Resources

U.S. GOVERNMENT PRINTING OFFICE
38-454 O WASHINGTON : 1984

5541-75

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NATIONAL CHILDHOOD VACCINE-INJURY COMPENSATION ACT

THURSDAY, MAY 3, 1984

U.S. SENATE,
COMMITTEE ON LABOR AND HUMAN RESOURCES,
Washington, DC.

The committee met, pursuant to recess, at 9:38 a.m., in room 562, Dirksen Senate Office Building, Senator Paula Hawkins (acting chairwoman of the committee) presiding.

Present: Senator Hawkins.

OPENING STATEMENT OF SENATOR HAWKINS

Senator HAWKINS. Good morning.

Today we are holding a hearing, the fourth in a series on the child immunization program. Today we are going to focus on the Hawkins bill, Senate 2117, the National Childhood Vaccine-Injury Compensation Act.

Out of necessity, this hearing will focus on the costs and regulatory burden that might be imposed by this legislation. But, to remind us why this legislation is necessary, I would first like to show a short video presentation produced by Wendy Scholl of Florida, a witness at an earlier hearing. This tape shows pictures of children in Florida who suffered injuries due to apparent adverse reactions to vaccines.

Would you show that, please?

[Whereupon, a video tape was viewed.]

Senator HAWKINS. Thank you.

My intent in sponsoring this legislation and holding these hearings is not to frighten parents away from immunizing their children against childhood diseases, nor is it to assess any blame. My intent is simply to improve our Nation's immunization program so that it better achieves its original goal of safeguarding our children's health.

Our previous hearings identified a number of areas that need to be addressed: the general childhood immunization program; the increasing costs of the vaccines; and the findings of the Federal task force report on pertussis, the most controversial of the seven childhood vaccines. Testimony presented at those earlier hearings demonstrated the need for a better vaccine for pertussis, the need to continue our search for safer and more effective vaccines, the need for a better recordkeeping system, the need for a better system of reporting adverse reactions to vaccines as well as incidences of the actual disease, the need for better communication between parent and physician, and the need for a better method of compensating those few children injured by adverse reactions to childhood vaccines.

The legislation we are considering today addresses all of these needs. Although compensation of the injured children is a key component of S. 2117, the other provisions of this bill are of equal importance, perhaps more important, because they are designed to improve the entire immunization program to prevent the injuries in the first place.

These provisions include mandatory recordkeeping by the health professional of the date, dosage, vaccine manufacturer, and lot number for each immunization given; mandatory reporting of adverse reactions occurring within a specified period of time following immunization; required studies of the relationship between vaccination and certain illnesses, injuries, and conditions; development of tests or procedures to determine categories of children who may be particularly susceptible to an adverse reaction; and development of parent information materials on the risks of vaccination, the risks of the diseases, and what reactions and signs the parent should monitor and report to the physician.

Despite the tremendous progress that we have made in safeguarding our children against deadly childhood diseases, we cannot afford to be complacent. Too many children have died, and too many have been injured from adverse reactions to the vaccines as well as the diseases themselves. Too many parents have lost faith in our vaccination program.

I think inaction is what we should fear, not steps designed to improve the childhood immunization program. Without our health—and our children's health—we have nothing. With it, we have the potential for everything.

Before we hear from the first panel of witnesses, we will receive for the record the prepared statements of Senator Hatch, chairman of the full committee, and Senators Kennedy, Grassley, and Thurmond.

[The statements of Senators Hatch, Kennedy, Grassley, and Thurmond follow:]

OPENING STATEMENT OF SENATOR HATCH

Senator Hatch. I am pleased to see full Labor and Human Resource Committee hearings today to address a small but significant public health problem—the incidence of harmful and occasionally even fatal reactions to vaccines administered to children. As we discuss unfortunate incidence of harm resulting from vaccines, I hope we will not lose sight of the miracle which has been from their use.

Childhood immunization is perhaps the single most successful public health effort in the history of the world. Widespread epidemics of common childhood diseases were once fatal to tens of thousands of infants and children every year. Thanks to immunization programs, such disasters are not history.

Sadly, the great success of immunization programs is not fully appreciated by the general public and perhaps not even by researchers. Our public health officials must combat parental laxity in getting children immunized. On the other hand, insufficient research focus has been placed on the eliminating of adverse reactions to vaccines. For example, we need to learn about the incidence of side effects and how we can prevent them happening in the future.

As we consider these very real problems, I want to make certain that our doubts and fears about immunization not overshadow the great benefits that have resulted from widespread immunization of children. I believe it would be a tragedy if our citizens were to lose faith in public vaccination programs which have been so important and effective in saving lives and improving health.

I want to commend my colleague, Senator Hawkins, for her interest and leadership in our childhood immunization program. She has spent many months investigating issues related to vaccine-related injuries and how we might manufacture safer vaccines. She has also developed legislation to provide compensation for victims of vaccine-related injury. On November 17, 1983, she introduced the National Childhood Vaccine-Injury Compensation Act (S. 2117). This legislation was developed in conjunction with physicians and parents of vaccine-injured children, and is a first step in the development of a method of compensation for such injuries.

As these hearings proceed, I welcome the opportunity to learn more about issues related to this legislation. There is conflicting data on the cost of S. 2117, there are differing opinions on how we might finance compensation, and concerns about qualifications for such compensation. Therefore, I welcome our witnesses today and look forward to their testimony. I hope they will provide us with important information we will need to thoroughly consider this issue.

OPENING STATEMENT OF SENATOR KENNEDY

Senator **Kennedy**. Madam Chairman, today the Labor Committee meets to consider a very important issue, the question of whether the Congress should enact legislation which would create a National Childhood Vaccine Compensation Program. There appears to be a growing concern among professionals, parents and administrators that some type of vaccine injury compensation program is necessary. We must preserve our national policy that a vaccination program is an excellent way to reduce the frequency of a number of infectious diseases and to avoid the many ill effects those diseases bring upon their victims. In addition, to the obvious question of avoiding the pain and suffering that infectious diseases cause, there is the additional consideration of reducing the costs incurred by diseases that may be preventable; clearly, given the high cost of health care in America today, any mechanism which reduces the need for hospitalization, reduces the cost of treatment and rehabilitation and reduces the cost and sorrow of death, is welcome.

However, we have come to recognize that despite the overwhelming social benefits derived from our childhood immunization program, there are obvious and painful costs. Even when vaccines are properly manufactured, distributed and administered, there will be a case of paralytic polio which will result from the administration of each 5 million doses of polio vaccine; there will be a serious neurological injury which will result from every 300,000 doses of DTP vaccine, and in rare cases there are severe consequences from the administration of MMR vaccines. These few but important injuries create doubts and fears in our National Childhood Vaccination Programs, doubts and fears that erode the confidence of caring parents. These few injuries also create the threat of substantial liability for the manufacturers and distributors of our Nation's supply of vaccine.

We live in an imperfect world. There is no such thing as certainty in the delivery of medical treatments, and there is no such thing as certainty in the administration of our Nation's vaccination programs. I do not think that we can insist on a vaccination program that guarantees no injuries and no consequences. If we required that kind of assurance, we would rarely do anything to protect the health of the American people. I made this observation 5 years ago as the chairman of the Subcommittee on Health and Scientific Research when we considered liability issues associated with the swine influenza immunization program, and I repeat it here.

We would sacrifice much that is good in the pursuit of the perfect. However, we cannot ignore the pains and suffering of those few but inevitable victims of our national immunization program. We cannot ignore those parents who have doubts and fears.

We must be able to get vaccines to children in the right time and place, at an acceptable cost and without creating exorbitant and unpredictable legal difficulties. We must be able to assure parents that when their children are the victims of an appropriate and rational national policy, a compassionate Government will assist them in their hour of need. We cannot tolerate a system which discourages immunization, increases the risks to the very children in need of protection, and encourages litigation within a tort system which awards few handsomely and sends others equally aggrieved away penniless.

On the other hand, we should not propose a system which is economically and politically unreasonable. We cannot ignore the fact such a proposed system would benefit no one.

Today, the Labor Committee will hear the honest and candid comments of our witnesses. I am sure that the answers they provide and the questions that they raise will help us to develop a national vaccine injury compensation program that is fair, equitable and reasonable.

OPENING STATEMENT OF SENATOR GRASSLEY

Senator **Grassley**. I want to commend Senator Hawkins for her efforts to bring systematic and responsible attention to the issue of vaccine-related injuries. The three previous hearings she has held on this topic have identified a number of goals we should strive to achieve.

First, we should strive to maintain public confidence in our immunization programs. As a number of witnesses stated at earlier hearings, and as I believe some of today's witnesses will also state, immunization of children has been spectacularly successful. A number of life-taking children's diseases have either been eliminated or all but eliminated as a result of our immunization programs. Furthermore, knowledgeable parties agree that, for individuals, the benefits of immunization outweigh the risks involved. It is important to make this point because many younger parents may have no memory of the devastating effects which epidemics of childhood diseases can have. Physicians who participate and who competently follow currently accepted practice must be able to feel confident that they will not be censured or sued as a consequence of their participation.

Second, although the incidence of adverse effect is very low, we should satsify ourselves that we are doing all that it is possible to do to eliminate all adverse effects of vaccines. One important priority should be to develop better, safer, vaccines. A second important priority should be to try to be sure that parents and physicians are well informed about the possible risks involved, and particularly about symptoms of adverse vaccine reaction, so that remedial steps can be taken immediately if a recipient appears to have adverse reactions.

Third, we should satisfy ourselves that we are doing all that it is possible to do to improve our knowledge of the extent, patterns, and causes of adverse reactions to vaccines. There appears to be a concern in some quarters at the present time that we do not have reliable knowledge about the extent, patterns, and causes of such adverse reactions. It is argued that this is partially a problem of inadequate recording of data about such vaccines and vaccinations, and partially a problem of inadequate reporting about adverse reactions. The establishment of causal relationships between particular vaccines and adverse reactions they might engender is very important also. Apparently at present a temporal association is the usual basis for concluding that a particular child might have experienced a vaccine-caused episode. Clearly, and particularly if this committee wishes to consider a Vaccine Injury Compensation Program, we should satisfy ourselves that enough is being done to help us better understand the causal relationships between adverse events and vaccines. A temporal association is not enough.

Fourth, we have to ask ourselves whether our present system of compensating people who are injured by vaccines is equitable and reasonable—that it compensates in a fair and timely way in those cases where it is unambiguously demonstrated that a particular vaccine caused damage. In all of our States, vaccination is required before a child will be allowed to enter public school. Federal, State, and local government officials urge all parents to immunize their children. For all practical purposes, immunization programs have become obligatory. Should a child sustain injury as a consequence of such an immunization program, it hardly seems fair that that child or its parents should sustain the entire burden of the consequences which may follow.

Our present system may also have contributed, through large liability awards, to raising vaccine prices, and to causing American companies to leave the field of vaccine production. Just how important liability awards have been in causing these effects is not clear. But in any case, it is therefore argued that some sort of compensation program is a good idea; that creation of such a program would help relieve the burden on children who sustain injury and their families, and help ensure that American manufacturers continue to produce vaccines.

S. 2117 is an effort to achieve some of these goals. I look forward to the testimony the committee will take today for the help it can give us in deciding whether everything that should be done on these problems is being done, and, if not, whether S. 2117 lays out the best ways to proceed.

OPENING STATEMENT OF SENATOR THURMOND

Senator **Thurmond**. Madam Chairman, it is a pleasure to receive testimony today concerning S. 2117, the National Childhood Vaccine-Injury Compensation Act.

Madam Chairman, one of the most significant achievements of science and medicine in the last century has been the development of vaccines which protect our children from a number of devastating diseases. While it is true that adverse reactions occasionally occur in vaccine recipients, it is impossible to measure the pain and suffering that has been avoided through the immunization of children.

I want to commend Senator Hawkins for her recognition of the problems experienced by those who suffer adverse reactions to vaccines and their families, and for her efforts to address those problems through the legislation we will consider today.

However, I have reviewed the prepared testimony of Dr. Brandt for this hearing and I believe he has raised some very important questions and concerns about S. 2117. Dr. Brandt's most serious concerns relate to the broad list of compensable conditions included in the bill and the level of payments established by the bill.

So, I look forward to the discussion today of these issues and to the testimony of all the distinguished witnesses who will testify.

Senator **Hawkins**. I would like to welcome Dr. Brandt back with us today, and Dr. Mason and Dr. Hinman to the hearing today. I believe this is the third time that Dr. Hinman has testified before our committee on this issue of childhood immunization, but I think we are making progress with each hearing.

Dr. Brandt, we would like to begin with you, please.

STATEMENT OF EDWARD M. BRANDT, JR., M.D., ASSISTANT SECRETARY OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY DR. JAMES O. MASON, DIRECTOR, CENTERS FOR DISEASE CONTROL; AND DR. ALAN HINMAN, IMMUNIZATION DIVISION, CENTERS FOR DISEASE CONTROL

Dr. **Brandt**. Thank you very much, Madam Chairman.

With your permission, I would like to submit my entire testimony for the record, and only summarize it here.

Immunization of children is one of the most spectacularly successful preventive health measures available. Through the appropriate use of vaccine, smallpox has been eradicated from the earth. In this country we have also essentially eliminated diphtheria, tetanus, and poliomyelitis as diseases of children. We are on the verge of achieving elimination of measles as a native disease and are beginning to intensify our efforts in order to hasten the ultimate elimination of rubella.

These achievements have had a dramatic impact on the morbidity that used to be considered an inevitable part of growing up. Thousands of children are now alive and well who would have died of these diseases if our modern vaccines had not been developed.

Current vaccines are both safe and effective. However, they are neither perfectly safe nor perfectly effective. Occasionally they will fail to provide the protection desired, and occasionally they cause something not desired—an adverse reaction. The challenge in vaccine development is to maximize efficacy while minimizing the risk of adverse effects. This balancing of benefits and risks is complicated by the difficulties in establishing a causal relationship between the administration of a vaccine and the occurrence of an adverse event.

A wide array of conditions, many with severe or fatal consequences, may affect children. Many of these are of unknown cause. Since almost all infants receive vaccines during these same months, it is inevitable that some of these conditions will occur in temporal association with receipt of a vaccine, although not caused by the vaccination. It is equally true that properly manufactured and administered vaccines can, on occasion, cause unavoidable damage. Despite careful study of individual circumstances, it is often impossible to state with certainty whether or not vaccine has actually played a role in the development of an adverse event. It is appropriate, therefore, to be cautious in ascribing a causal role to the vaccine in individual cases unless studies have clearly demonstrated that an excess number of such adverse conditions occur among vaccine recipients.

We are very concerned about the problem of vaccine-associated injuries and are eager to minimize their occurrence. We have established an interagency work group to monitor vaccine development, production, and usage. We have carried out or funded several studies concerning vaccine reactions, and these, of course, were summarized in a report submitted to you, Madam Chairman, last year.

We have established a monitoring system for adverse events following immunization in the public sector at the CDC, and the FDA continues to receive reports from the private sector.

Although the occurrence of adverse events following immunization can be minimized, it cannot be eliminated entirely. Thus, there will always be a small number of individuals who are harmed by the vaccines that protect our society. S. 2117 addresses an important issue—compensation for individuals who are injured as a result of receiving vaccines which are universally recommended and often required by State laws. The bill has a laudable goal and in general seems to reflect recommendations that have been made to the Department over the past several years by many different groups. However, the bill has major weaknesses which make it impossible to support. Of special concern are the broad list of compensable conditions, the level of payment established, and the retroactivity provisions. These factors interrelate to provide a significant disincentive to childhood vaccination programs. In my prepared testimony I discuss all of these concerns in more detail.

Our major concern about the list of compensable conditions is that the bill establishes a strong presumption that vaccine is responsible for essentially any adverse condition that happens after immunization unless there is incontrovertible evidence of other causation. This presumption of guilt would undermine public confidence in immunizations.

Furthermore, the criteria for qualification are broad enough to permit compensation in a wide variety of circumstances including situations in which the relationship of the vaccine to the injury is not clear.

We also have given some examples, Madam Chairman, of computations of the compensation, and, in addition, would point out that the Congressional Budget Office has estimated that the cost of this bill to the Federal Treasury, not including the increase in the cost of the vaccine doses, for the first 3 years would be approximately $4.9 billion.

As to retroactivity, the bill provides that any designated event which occurred before enactment would also automatically be eligible for compensation. Given the lack of specificity of eligibility criteria, one can envision a number of situations as outlined in the testimony.

There are numerous additional problems with the program that this bill would establish, and I have mentioned some of them in the testimony.

Madam Chairman, this is a very complicated area. It is one that does demand some sort of solution, and one in which it is obvious that there is not a single simple solution.

We are not convinced that a Federal program is needed to accomplish this. As well-intentioned as S. 2117 is, its provisions, in our view, complicate an already complex situation rather than help to resolve it. For these reasons, the administration opposes the bill. We will continue, however, to work with this committee on the important policy issues addressed by this legislation.

I and my colleagues would be happy, Madam Chairman, to answer any questions.

[The prepared statement of Dr. Brandt follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Washington DC 20201

STATEMENT OF

EDWARD N. BRANDT, JR., M.D.
ASSISTANT SECRETARY FOR HEALTH

PUBLIC HEALTH SERVICE
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES
UNITED STATES SENATE

MAY 3, 1984

Mr. Chairman and members of the Committee, I am pleased to appear before you today to discuss S. 2117, the "National Childhood Vaccine-Injury Compensation Act." I am accompanied by Dr. James Mason, Director of the Centers for Disease Control, and Dr. Alan Hinman, Director of the Division of Immunization of the Centers for Disease Control.

Immunization of children is one of the most spectacularly successful preventive health measures available. Through the appropriate use of vaccine, smallpox has been eradicated from the earth. In this country we have also essentially eliminated diphtheria, tetanus, and poliomyelitis as diseases of children. We are on the verge of achieving elimination of measles as a native disease and are beginning to intensify our efforts in order to hasten the ultimate elimination of rubella. These achievements have had a dramatic impact on the morbidity that used to be considered an inevitable part of growing up. Thousands of children are now alive and well who would have died of these diseases if our modern vaccines had not been developed. Current vaccines are both safe and effective. However, they are neither perfectly safe nor perfectly effective. Therefore, occasionally they will fail to provide that which is desired (protection), and occasionally they will cause something that is not desired (an adverse reaction). The challenge in vaccine development is to maximize efficacy while minimizing the risk of adverse effects. After a vaccine is licensed and put into use, it is also important to maintain surveillance to ensure that the benefits of vaccination continue to outweigh the risks. This balancing of benefits and risks is complicated by the difficulties in establishing a causal relationship between the administration of a vaccine and the occurrence of an adverse event.

The months of infancy and early childhood are fraught with a multitude of dangers. An array of conditions, many with severe or fatal consequences, may affect children. Many of these conditions are of unknown cause. Since almost all infants receive vaccines during these same months, it is inevitable that some of these conditions will occur in temporal association with receipt of a vaccine, although not caused by the vaccination. It is equally true that properly manufactured and administered vaccines can, on occasion, cause unavoidable damage. Despite careful study of individual circumstances, it is often impossible to state with certainty whether or not vaccine has actually played a role in the development of an adverse event. Since virtually all adverse conditions associated with vaccination also occur unrelated to vaccination, it is appropriate to be cautious in ascribing a causal role to the vaccine unless studies have clearly demonstrated that an excess number of such adverse conditions occur among vaccine recipients.

It is not clear what proportion of current vaccine prices is made up of the current and anticipated future costs of vaccine injury claims and litigation. Tables 1 and 2, which I am including with the written testimony, indicate the per-dose cost of different vaccines in the public and private sectors and give some estimate of the magnitude of the childhood vaccine market in the United States at present. In summary, we estimate the total childhood vaccine market in the United States to be approximately $146 million per year.

We are very concerned about the problem of vaccine-associated injuries and are eager to minimize their occurrence. We have established an interagency work group to monitor vaccine development, production, and usage. We have carried out or funded several studies concerning vaccine reactions; those were summarized in a report submitted to Senator Hawkins last year. We have established a monitoring system for adverse events following immunization in the public sector at the Centers for Disease Control, and the Food and Drug Administration continues to receive reports from the private sector. Information from these systems is used to help us evaluate the significance of events which occur following the receipt of vaccines. Recently, the Public Health Service Immunization Practices Advisory Committee (ACIP) modified its recommendations about the use of pertussis vaccine in infants and children who have previously had convulsions, based largely on data from the CDC monitoring system. Since no vaccine is totally without some risks, this continued balancing of the risks and benefits of immunizations is essential and is an integral part of our activities. To try to assure parental understanding of risks and benefits of vaccines, we have developed and implemented in the public sector a series of "Important Information Statements" designed to present the most important facts concerning vaccines. These forms are updated periodically.

Although the occurrence of adverse events following immunization can be minimized, it cannot be eliminated entirely. Thus, there will always be a small number of individuals who are harmed by the vaccines that protect our society. S. 2117 addresses an important issue--compensation for individuals who are injured as a result of receiving vaccines which are universally recommended and often required by State laws. It establishes a mechanism by which an injured party can receive compensation without having to prove negligence. It guarantees that those who experience certain designated events will receive compensation for medical expenses, special education and rehabilitation, forgone wages, and pain and suffering. The bill has a laudable goal and in general seems to reflect recommendations that have been made to the Department over the past several years by many different groups, including national immunization work groups and the American Academy of Pediatrics. However, the bill also has major weaknesses which make it impossible to support. Of special concern are the broad list of compensable conditions, the level of payment established, and the retroactivity provisions. These factors interrelate to provide a significant disincentive to childhood vaccine programs. I will discuss each of these concerns briefly.

1. The list of compensable conditions. The bill establishes a list of acute events covered and the time period in which these must occur in relation to vaccination in order for the vaccine recipient to qualify for compensation. The event must require hospitalization and incur expenses of at least $2,500, or must involve the death of the recipient. Although some of the conditions proposed in the bill have been temporally associated with receipt of pertussis-containing vaccine, scientific consensus does not exist that all of these conditions are caused by the vaccine and likely to lead to permanent damage. Serious questions remain both about immediate causation of these conditions and the relationship of these conditions to sequelae.

   In addition, the bill is so vague as to allow virtually any event following one of the listed events to be considered as causally related. The bill establishes a strong presumption that the vaccine is responsible for essentially any adverse condition that happens after immunization unless there is incontrovertible evidence of other causation. This presumption of guilt would undermine public confidence in immunizations.

Several items listed in the "vaccine injury" table occur relatively commonly after receipt of pertussis-containing vaccine. Table 3 summarizes the estimated annual frequency of events listed as compensable in the bill. An unknown but substantial proportion of those events likely would meet the criterion of hospitalization with medical expenses totalling $2,500. The level of compensation that would be awarded to these individuals cannot be estimated with certainty. Given the current level of medical costs and the incentive which may be posed by the existence of the compensation system, it seems likely that a substantial proportion of persons with these conditions might be hospitalized (sometimes unnecessarily) and incur expenses in excess of $2,500. The criteria for qualification are broad enough to permit compensation in a wide variety of circumstances, including situations in which the relationship of the vaccine to the injury is not clear. For example, the bill could potentially allow for compensation of a child who had a simple febrile seizure before immunization if the child had a similar febrile seizure after immunization and subsequently had two further febrile seizures within the next year.

Additionally, the "other appropriate factors" to be taken into consideration to determine compensation include prolonged sleeping with difficulty arousing, a condition practically impossible to define objectively. A single fever of 105°F accompanied by irritability (not further specified) would also be viewed as compensable. Finally, it should be noted that the manifestation must not necessarily have been recognized or recorded within the timeframe specified but could be inferred to have occurred. This creates a great possibility for inaccurate recollection of events. The bill also indicates that any "significant worsening of a preexisting condition will be treated the same as if it were evidence of a newly arising condition." Thus, a child who had a convulsion before vaccination as a result of some organic brain damage, and subsequently had worsening of that condition as a result of the natural progression of the disease, might have received a dose of vaccine within 7 days before having one of the convulsions. This bill would encourage considering that the entire condition was brought about by vaccination. An infant recognized to have a serious progressive neurological disorder might be vaccinated and thus become eligible for compensation for the expensive care and maintenance needed by the child for a preexisting condition not affected by vaccination.

2. Compensation levels. The levels of compensation specified in the bill include amounts which are apparently designed to make the compensation system an attractive alternative to the tort system. Although listed as maximums, these values seem likely to become the norm. In addition, $100,000 could routinely be awarded to each injured party for "pain, suffering, and emotional distress" in addition to the other costs which are listed. The bill mandates, rather than simply permits, award for pain and suffering. Coupling this with the allowable attorney's fees (20-25 percent depending on whether or not there is an appeal) and the extremely broad definition of compensable events, the costs of this bill would be enormous, far outweighing the current costs of illness truly caused by vaccine. The surtax

(proposed as the mechanism of financing the compensation) subsequently imposed on vaccines could render their price prohibitive.

Table 4 lists the range of estimates in 1980 dollars of the likely direct and indirect medical costs associated with selected events. The range is quite broad, reflecting the range in possible outcomes of different conditions. For example, estimates of costs associated with convulsion following DTP vaccination range from $259 to $869,574. These values do not include pain and suffering. There is marked variation between high and low estimates, depending on severity of the condition and the sequelae; at present we cannot project the likely distribution. Some of the events listed as compensable in the bill are relatively frequent, and even though there is little evidence of permanent damage associated with them, any projectable frequency of severity and outcome would result in inordinate expenditures, given the level of compensation proposed.

As an example, Table 3 shows that the estimated annual frequency of convulsion, collapse, and high-pitched unusual cry might exceed 35,000 individual events. These events have not been established to be associated with permanent damage. However, if 10 percent of them resulted in hospitalization with medical expenses of $2,500, thus qualifying for compensation, actual medical reimbursable expenses would total $8,750,000. If all of these individuals were also awarded $10,000 for "pain and suffering," this category would total $35,000,000. Along with the additional 20 percent for lawyers fees, this could come to an annual total of over $52 million, even though no permanent damage had occurred and actual expenses were $8.7 million.

This figure is clearly far in excess of the true cost of these events and would require imposition of a surtax on DTP vaccine of approximately $52 million (nearly $3/dose). This would more than double the current price of the vaccine in order to pay for events not having permanent consequences and not considered clearly related to vaccine administration.

By contrast, payment for encephalopathies occurring within 7 days of receipt of a pertussis-containing vaccine and accompanied by residual deficit 1 year later (a condition which might truly represent lasting damage potentially resulting from vaccine) would cost approximately the same total amount. For example, if there are 50 of these instances per year and all have direct and indirect costs at the upper range of the estimate, this would total approximately $40 million. Adding to that the maximum $100,000 each for pain and suffering and then adding 20 percent lawyer's fees would yield a total cost of approximately $54 million. These are just two examples. The Congressional Budget Office has estimated that the cost of this bill to the Federal Treasury (not including the increase in the cost of Federally-funded vaccine doses) for the first three years would be $4.9 billion, with an expectation that the annual cost of $225 million for each succeeding year will be covered by the surcharge revenues.

3. Retroactivity. The bill provides that any designated event which occurred before enactment would also automatically be eligible for compensation. Given the lack of specificity of eligibility criteria, one can envision situations in which parents with disabled or retarded children, many now grown, might make claims based on their

> recollection that within the appropriate time period following receipt of vaccine their child had manifested "prolonged sleeping with difficulty arousing" or "high-pitched unusual screaming" which was neither noted nor recorded at the time. The difficulty in proving or disproving such allegations would almost certainly result in a large number of individuals receiving compensation whether or not it was merited, further driving up the costs of vaccination.

There are numerous additional problems with the program that this bill would establish, and I will mention some of them. The proposed program does not represent an exclusive remedy; individuals may choose whether to pursue the tort system or the compensation system. This provision is inconsistent with one of the major stated purposes of the bill, which is to relieve the pressure of litigation on vaccine manufacturers. Also troublesome are the open-ended borrowing from the Treasury, and the procedural provisions, under which injured parties would make their claims in an ex parte proceeding, leaving it unclear as to whether the Secretary and the Fund have a role in the decision to compensate. These factors interrelate to make the costs of the bill prohibitive and far in excess of actual expenses.

Mr. Chairman, this is a very complicated area and one in which it is obvious that there is not a single simple solution. However, we are not convinced that a Federal program is needed to accomplish this and are certain that S. 2117 will not do so. As well-intentioned as it is, the provisions of S. 2117 complicate an already complex situation, rather than help to resolve it. For the reasons I have outlined and for several others, we oppose the bill. We will continue to work with this committee on the important policy issues addressed by this legislation. I would be happy to discuss any questions you might have.

TABLE 1

AVERAGE[1] VACCINE PRICES/DOSE

MARCH 1984

VACCINE	PUBLIC SECTOR	PRIVATE SECTOR
DTP	$1.43	$ 1.66
DT	0.34	0.63
Td	0.28	0.57
OPV	0.73	4.27
MMR	5.40	12.08

[1] Assumes equal market share for all manufacturers of DTP/DT/Td and mid-point price for a given manufacturer if there was a range in public sector prices.

TABLE 2

ESTIMATED CURRENT ANNUAL SIZE OF U.S. VACCINE MARKET[1]

	DOSES DISTRIBUTED (MILLIONS)[2]			ESTIMATED COST (MILLIONS)		
VACCINE	PUBLIC	PRIVATE	TOTAL	PUBLIC	PRIVATE	TOTAL
DTP[3]	6.04	12.75	18.79	$ 8.64	$21.17	$ 29.81
DT[3]	0.33	0.71	1.04	0.11	0.45	0.56
Td[3]	3.03	6.39	9.42	0.85	3.64	4.49
OPV	7.31	12.46	19.59	5.21	53.20	58.46
MMR[4]	2.61	3.25	5.86	14.09	39.26	53.35
TOTAL			54.70			$146.62

[1] Based on March 1984 prices and 1983 distribution.

[2] Total from 1982 Biologics Surveillance data, public sector usage from Immunization Project reports; private sector usage is the remainder.

[3] The public/private mix of these formulations is based on Biologics Surveillance data for distribution of each formulation, and public sector use of DTP/DT/Td as a proportion of total use.

[4] Assumes all measles, mumps, and rubella vaccines are sold as MMR, which is true for 85% of the total for each antigen.

TABLE 3

ESTIMATED NUMBERS OF SPECIFIED EVENTS PER YEAR[o]
TEMPORALLY ASSOCIATED WITH THE ADMINISTRATION OF VACCINES, U.S.
BASED ON ANNUAL VACCINE USE AND
BEST ESTIMATE OF RATES OF OCCURRENCE

EVENT	VACCINE	TIME PERIOD	ESTIMATED ANNUAL FREQUENCY[x]
Anaphylaxis	All except OPV	24 hours	40-60[1]
Convulsion	Pertussis containing	7 days	9,000[2]
	Other except OPV	30 days	5,000[3]
Encephalopathy	DTP	7 days	total 150
or encephalitis			with residua 50[4]
	MMR	30 days	4[5]
Fever of 105°	DTP	72 hours	25,000[2]
High-pitched screaming	DTP	72 hours	17,000[2]
Persistent crying	DTP	72 hours	450,000[2]
Collapse	DTP	72 hours	9,000[2]
Thrombocytopenia	DTP	30 days	--[6]
Polio	OPV	variable	8[7]

[o] Based on annual birth cohort of 3.5 million children

[x] Except for OPV the estimated number of doses which should be administered according to current recommendations, assuming 90% coverage and an equal risk with each dose of a series. OPV estimate based on average annual number of vaccine-induced cases reported 1969-1982.

Sources:
1. Swine flu experience
2. Cody et. al. and Hinman & Koplan
3. Landrigan & Witte
4. Miller et. al. and Hinman & Koplan
5. Landrigan & Witte
6. The relationship is in question and current data do not permit an estimate.
7. 1969-1982 experience

TABLE 4

ESTIMATED RANGE OF DIRECT AND INDIRECT COSTS OF SPECIFIED EVENTS OCCURRING TO INFANTS 1 YEAR OLD, DISCOUNTED AT 2.5%

EVENT	VACCINE	RANGE OF COSTS
Anaphylaxis	DTP	$ 95-825,769
Convulsion	DTP	259-869,574
Encephalitis	DTP	2,487-849,474
	Measles	1,313-927,533
Paralysis	OPV	1,766-825,550

Source: NCHSR Study

Senator **Hawkins**. Thank you, Dr. Brandt.

Has the administration fully investigated the causes and the potential implications in the decline of the number of pharmaceutical manufacturers producing vaccines in the United States?

Dr. **Brandt**. I think the key word is "fully." We have investigated the causes and the potential implications. I am not personally satisfied that we have fully investigated or that we have a full understanding. It seems clear that there are a number of reasons for this that vary somewhat from manufacturer to manufacturer as well.

Senator **Hawkins**. Is it your understanding that we are down to three manufacturers for DPT and only one for measles, mumps, and rubella?

Dr. **Hinman**. That is correct, Madam Chairman. There is also only a single manufacturer of oral polio vaccine in the United States at the present time.

Some of the factors involved include market forces. The market is a predictable one since a finite number of children are born and a finite number of doses of vaccine will be required, but we do not, as Dr. Brandt has said, understand all of the reasons that are involved in the decrease in number of manufacturers.

Senator **Hawkins**. Are you investigating that?

Dr. **Hinman**. We have had conversations with the manufacturers. However, as I understand it, some of this is viewed as being, privileged business information.

Senator **Hawkins**. Is the Government prepared to take over the responsibility of producing the vaccines if the manufacturers do decide to stop producing vaccine?

Dr. **Brandt**. We are not prepared to begin to produce the vaccines. We certainly will be prepared to deal with the manufacturers to try to work out some way to keep vaccines being produced if, in fact, all of the manufacturers were to find it necessary to cease production.

We have no evidence from my conversations with all of the vaccine manufacturers that there is any threat of that on the horizon, by any stretch of the imagination. But this program is so important to the health of children that we would certainly work with vaccine manufacturers to try to solve the problem.

Senator **Hawkins**. Have the prices of the individual immunizations gone up as the number of manufacturers has gone down?

Dr. **Brandt**. The price has gone up, and, indeed, the number of manufacturers has gone down. I think, Madam Chairman, in my testimony, table I shows the current prices of the vaccines.

Senator **Hawkins**. It is my understanding that it has gone from $3 to $40 a vaccine. Is that correct? For a shot?

Dr. **Hinman**. The price of vaccines has risen, yes, Madam Chairman. It is possibly worth pointing out, however, that even when there was only a single manufacturer of one of the vaccines that comes to mind quickly—measles, mumps, and rubella—the price of that vaccine did decrease over a period of several years in the early and mid-1970's, and it has been increasing lately.

The current price we pay in the Federal contract for a dose of measles, mumps, and rubella vaccine is $5.40.

Senator **Hawkins**. For our MMR?

Dr. HINMAN. That is correct.

Senator HAWKINS. What about DPT?

Dr. HINMAN. We do not presently have a Federal contract for DPT vaccine, but the average cost in the public sector under State contract—if one takes the three manufacturers, the current prices they are charging, and average those—it comes to $1.43 a dose. About a year ago it was about 68 cents.

Senator HAWKINS. Sixty-eight cents a year ago, and it has gone up to what?

Dr. HINMAN. $1.43.

Senator HAWKINS. Has the administration considered requiring a manufacturer to develop or produce one vaccine as a condition to Federal Government purchase of another?

Dr. BRANDT. We have not seriously considered that, Madam Chairman, largely because we have not seen an immediate threat by any manufacturer to withdraw from the vaccine market. I think our alternatives in case this were to occur would be, one, to deal with the manufacturers to see if we could work with them to resolve this problem in some other way than to force them into this kind of situation.

Senator HAWKINS. It does not bother you that we just have one manufacturer for MMR vaccine?

Dr. BRANDT. Well, it bothers me in one way, in the sense that——

Senator HAWKINS. Would that be called a monopoly?

Dr. BRANDT. Yes, that is what I would call it, I guess, but I think, on the other hand, that production of these vaccines does require a great deal of scientific and manufacturing ability. As long as the vaccines are available, I am not concerned about—overly concerned about—the fact that——

Senator HAWKINS. Do you know how much stock the one manufacturer has?

Dr. BRANDT. I am sorry?

Senator HAWKINS. How much stock—do they have an inventory?

Dr. BRANDT. I do not know for sure, but I think they usually maintain a 2-year supply.

Dr. HINMAN. Yes.

Senator HAWKINS. Two years?

Dr. BRANDT. Yes, Ma'am.

Senator HAWKINS. In the past the Federal Government has influenced the willingness of the private pharmaceutical companies to pursue the development of vaccines. Eli Lilly was given a contract for flu vaccine, and, more recently, the Michigan Department of Health and Biologics was given a contract to develop a safer pertussis vaccine. Have you found these direct contracts successful?

Dr. HINMAN. The current contract for development of improved pertussis vaccine was not bid on by any of the current commercial manufacturers.

Senator HAWKINS. Why do you think that was?

Dr. HINMAN. I cannot respond to that. You might wish to ask the manufacturers.

Senator HAWKINS. I will. I just wondered if you had an opinion.

Dr. HINMAN. I think that Government-funded research in vaccine development has historically been of great utility.

Senator HAWKINS. The correlation between the Federal Government purchase of vaccines for the State vaccination programs and the reduction of disease seem pretty well established. Using measles as an example, in 1965 when Congress added measles to the community health service extension program, 6.1 million doses were distributed. But in 1969 and 1970, when no funds were appropriated for this program, only 4.9 and 4.5 million doses were distributed, and the reported incidences of measles increased from 25,826 cases in 1969 to 47,351 in 1970 and 75,290 in 1971. So the incidences of measles did not decrease until the program was refunded in 1971. So if we are concerned as a country about the outbreaks of pertussis, why don't you include it in your Federal immunization program?

Dr. HINMAN. We do include pertussis immunization as a part of the Federal immunization program. We have not to date established a consolidated Federal contract for the purchase of DPT vaccine. I think there have been two major reasons for that.

Until very recently, the price of DPT vaccine has been low enough that we did not feel we would save enough money by establishing a consolidated Federal contract to make it worth it.

The second item is that you have been talking about the problem of decreasing numbers of vaccine manufacturers. There are three manufacturers of DPT. Award of a single Government contract potentially would be a disincentive to the unsuccessful bidders.

Now we presently have a request for proposals for the purchase of diphtheria, tetanus, and pertussis vaccines under a consolidated Federal contract, both for the vaccine stockpile which we are presently establishing and for continuing use in the grant program.

Dr. BRANDT. I think, Madam Chairman, you have made an extremely important point early on, and that is the success of the immunization program. If I could take just a minute, I would like to cite just a few examples.

From 1980 through 1983, the number of reported vaccine-preventable diseases in this country in children fell by 71 percent in that 3-year period, from roughly 28,000 to roughly 8,000 cases. That is a dramatic improvement, due in large part to the vaccines.

Second, goals were set by Surgeon General Richmond in 1979 for immunization of this country to be achieved by the year 1990. At the end of 1983 we had achieved virtually all of those. So I think the immunization program has been remarkably successful in reducing the suffering and problems of young children.

It is, therefore, it seems to me, absolutely essential that this program be continued; that we continue our research on vaccines, both to develop new ones as well as to improve the ones that we have, and we certainly have that under way as a major activity.

Senator HAWKINS. Isn't it true, though, that DPT is the only combination of vaccines which isn't purchased by the Federal Government through consolidated contract?

Dr. HINMAN. If you are talking about childhood vaccines, that is correct. We do not purchase influenza vaccine or pneumococcal vaccine, either, which are other vaccines recommended for relatively widespread use.

I believe that, given the reflection of interest in State governments in getting a consolidated Federal contract for DPT vaccine, that it is quite likely we will have such a contract within the next several months.

Senator **Hawkins**. Within months?

Dr. **Hinman**. Within the next several months.

Senator **Hawkins**. I understand the FDA convened a group of experts in November 1983 to review the recent efforts and progress in improving the vaccine safety and to review studies of serious reactions to the DPT vaccine in children. Can you summarize the results of that meeting?

Dr. **Brandt**. I think, Madam Chairman, that actually it was not the FDA that convened that, but the World Health Organization. The meeting was in Geneva, and we had people from the Food and Drug Administration in attendance.

We will be happy to provide you with a summary of that and other material from that meeting. We will be happy to provide it to you for the record.

[Note: In the interest of economy, the material referred to was retained in the file of the committee.]

Dr. **Brandt**. Dr. Hinman wants to add something.

Dr. **Hinman**. There was one other meeting which may be the one to which you are referring in which the FDA and the NIH collaborated in bringing together a group of people to look at the issue of followup of studies for people who have been involved, children who have been involved, in studies of DPT reactions, specifically the study at the University of California, Los Angeles. I believe that may be the meeting to which you are referring.

The result of that was that a letter was sent to the principal investigator in Los Angeles in which the originally proposed study was not approved, but the statement was made that the FDA, the Government, would be interested in providing support for followup of the 18 children who were of particular interest. We have not received a response to that letter to my knowledge.

Senator **Hawkins**. You have not received a response?

Dr. **Hinman**. Not to my knowledge.

Senator **Hawkins**. Would you check that out and get back with us?

Dr. **Hinman**. Yes, Ma'am.

Senator **Hawkins**. Thank you, Dr. Hinman.

[Material supplied follows:]

[Note.—A report of this meeting is now being completed; a copy will be sent as soon as it is available. See attached letter from the World Health Organization.]

WORLD HEALTH ORGANIZATION ORGANISATION MONDIALE DE LA SANTE

Telephone Central/Exchange: 91 21 11
Direct: 91 2677/2620

In reply please refer to:
Prière de rappeler la référence: B5/445/9

Dr C.R. Manclark
Director, Pertussis Branch
Division of Bacterial Products
Office of Biologics
National Center for Drugs and Biologics,
Food and Drug Administration
Bethesda, Maryland 20205
Etats-Unis d'Amérique

4 June 1984

Dear Dr Manclark,

I should like to take this opportunity of thanking you for your participation in the Meeting on the Results of the WHO Collaborative Study on the Acellular DPT Vaccine. The discussions during these three days were extremely valuable and your own contribution helped to make the meeting and the report a very worth-while effort.

The report is now being finalized and a copy will be sent to you shortly.

I hope you had a safe journey home. We enjoyed having you with us in Geneva and I look forward to an early opportunity of meeting you again.

With kindest regards.

Yours sincerely,

Dr T. Kereselidze
Medical Officer
Bacterial and Venereal Infections

NATIONAL CENTER FOR DRUGS AND BIOLOGICS
OFFICE OF BIOLOGICS RESEARCH AND REVIEW

November 10, 1983

Meeting on Pertussis Vaccine: Status of Current Research

The following persons were present:

Harry Meyer - NCDB
Paul Parkman - NCDB
John Petricciani - NCDB
Elaine Esber - NCDB
Theodore C. Eickhoff - Presbyterian/Saint Luke's Medical Center
Dick Johnson - Johns Hopkins
Karin Nelson - NINCDS
Frederick C. Robbins - National Academy of Sciences
Barbara Iglewski - University of Oregon
Edward A. Mortimer - Case Western Reserve University
Neal Nathanson - University of Pennsylvania
Philip Dodge - Washington University
William S. Jordan, Jr. - NIAID
Carolyn Hardegree - NCDB
Kenneth Bart - CDC
David Klein - NIAID
Chuck Manclark - NCDB
Gerald Faich - NCDB
Harrison Stetler - CDC
John Robbins - NIAID
Jack Gertzog - NCDB
Don Burtstyn - NCDB
Bruce Mead - NCDB
Morris Schaeffer - NCDB
James Bilstad - NCDB
Kamal Mittal - NCDB

The meeting was convened at 9:00 a.m. in accordance with 21 CFR 14.1 (b)(5)(i) to discuss pertussis research. Topics covered included the current status of pertussis vaccines; review of information from recent pertussis studies; discussion of pertussis vaccine reaction information from CDC and FDA reporting systems and a review of those systems; review of an unsolicited proposal for a follow-up study of children with adverse reactions associated with DTP vaccination, and consideration of alternatives.

The development of whole and acellular pertussis vaccines was reviewed. Animal models were discussed and it was noted that the mouse protection test has not been correlated with human efficacy for any acellular vaccines which have been licensed as it has been for whole cell vaccines. Other animal models are being studied, but none have been correlated with human efficacy. Reports on the potency and efficacy of

Japanese acellular vaccines have not been confirmed in this country. Information on attempts to develop acellular pertussis vaccines in this country and to reduce the reactogenicity of whole cell vaccines was discussed. Much of this information is trade secret information not disclosable in accordance with 5 USC 552b(c)(4).

Adverse reaction (AR) reporting was discussed. The difficulty of evaluating AR on an international level was noted because of inconsistencies in international standards and definitions; different medical practices (e.g., the French frequently prescribe anticonvulsants prophylactically with pertussis vaccines); and differences in products attributable to different manufacturing methods. However, the National Childhood Encephalopathy Study in the United Kingdom was considered in some detail in addition to U.S. data. Serious adverse reactions to DTP as described in recent U.S. studies were reviewed (see Table 1, first attachment).

The FDA and CDC adverse reaction reporting systems were discussed. FDA biologic adverse reaction reports for pertussis containing vaccines are voluntarily provided on a monthly or quarterly basis by the major manufacturers although some manufacturers will report adverse reactions earlier, if, in their judgment, circumstances require this; they have no standard format; they do not generally provide sufficient denominator information. The reports are usually based on information voluntarily provided to the manufacturers by physicians. The CDC system does use a standard format, but all of the information which would be useful is not always provided. The CDC system depends primarily on reports originating with parents, through a health service physician, and occasionally, originating with a private physician. This system covers about 40 percent of vaccinations that include pertussis antigens. Efforts to strengthen both adverse reaction reporting systems are underway, but both systems currently provide useful information to health care scientists. It was noted that the current formats used by CDC for reporting adverse events following immunization could be misinterpreted, and a number of revisions were suggested.

An unsolicited contract proposal for follow-up of children with adverse reactions associated with DTP vaccination was reviewed. The unsolicited study proposes to evaluate a maximum of 18 children, although the number may be as few as 10 to 12, who had initially experienced a serious adverse reaction within 48 hours of immunization in a vaccine study conducted between 1977 and 1979. The study proposes that the vaccinated children be compared to matched controls. The proposed tests are neurologic examination, psychometric evaluation (Stanford-Binet) and HLA typing for 70 antigens. The general conclusion of the participants was that it is highly improbable that useful information could be obtained from the proposed study. Data for some of the parameters such as neurologic examination and psychometric evaluation would be uninterpretable because of the lack of comparable baseline data for the study subjects, thereby making it impossible to control the study for these variables. Given the small number of subjects in the study, there is very low probability of detecting any HLA associations, the one test in the proposal which was believed by the meeting participants to have any potential usefulness. Moreover, experience with other diseases has shown that a strong familial history of a disease is usually observed if HLA typing is to demonstrate any association with disease. Current information does not suggest a strong familial association with pertussis reactions. Interpretation of HLA results would also be further confounded by the fact that we appear to be dealing with 2 distinct subsets of adverse events, convulsive reactions and collapse reactions (hypotonic/hyporesponsive). One or two attendees at the meeting nevertheless believed that even with the deficiencies in the proposed study, the relatively quick access to subjects warranted support of the HLA part of the study because even though there was a low probability that it might yield useful information there was the feeling of interested parties that "something" should be done. This view was not shared by the majority of attendees. Use of the proposed study as a pilot study to provide information was considered and rejected as unuseful. It was the consensus of all consultants present, in addition to participants from NIAID, NINCDS, and CDC that the proposed study did not have scientific merit.

The view was expressed that although the proposed study did not deserve support from the standpoint of the science involved, an argument could be made that follow-up would be reasonable as a matter of medical care.

The group agreed that if vaccine associated reaction studies are to be done, other, more comprehensive studies with larger populations should be considered. However, the consensus of the participants was that the large funding which would be required to support studies of pertussis vaccine associated adverse events comparable to the National Childhood Encephalopathy Study in the United Kingdom is of lower priority than efforts to develop protective but less reactogenic pertussis vaccines.

SUMMARY OF SERIOUS ADVERSE REACTIONS TO DTP REPORTED IN FI[illegible] [illegible] STUDIES

	Reaction		
Study No	Crying/Screaming	Seizure	Hypotonicity/Hyporesponsiveness
1	0	0	0
2	591/1232 (48%)	0	0
3	4/253 (29%)	0	0
4	88/481 (18%)	1/481 (0.2%)	0
5	505/15752 (3%)	9/15752 (0.06%)	9/15752 (0.06%)

1. Hopkins, R.S. Reactions to DTP Vaccine, by Lot and Manufacturer: Results of a Survey in Montana. Third International Symposium on Pertussis, 300-303.

2. Barkin, R.M., Pichichero, M.E. (1979). Diphtheria-Pertussis-Tetanus Vaccine: Reactogenicity of Commercial Products. Pediatrics, 63, 256-260.

3. Murphy, M.D., Rasnack, J., Dickson, H.D., Dietch, M., and Brunell, P.A. (1983). Evaluation of the Pertussis Components of Diphtheria-Tetanus-Pertussis Vaccine. Pediatrics, 71, 200-205.

4. Gupta, U., Koranyi, K.I., McIlroy, M.A. (1982). Reactions to Diphtheria, Pertussis and Tetanus (DPT) Immunization in Children. Ambulatory Pediatric Association Abstract, Page 80.

5. Cody, C.L., Baraff, L.J., Cherry, J.D., Marcy, S.M., and Manclark, C.R. (1981). Nature and Rates of Adverse Reactions Associated with DTP and DT Immunizations in Infants and Children. Pediatrics, 68, 650-660.

U.S.C. 401 et seq.); sec. 1 et seq., Pub. L. 89-755, 80 Stat. 1296 as amended (15 U.S.C. 1451 et seq.), unless otherwise noted.

SOURCE: 44 FR 22351, Apr. 13, 1979, unless otherwise

Subpart A—General Provisions

§ 14.1 Scope.

(a) This part governors the procedures when any of the following applies:

(1) The Commissioner concludes, as a matter of discretion, that it is in the public interest for a standing or ad hoc policy or technical public advisory committee ("advisory committee" or "committee") to hold a public hearing and to review and make recommendations on any matter before FDA and for interested persons to present information and views at an oral public hearing before the advisory committee.

(2) Under specific provisions in the act or other sections of this chapter, a matter is subject to a hearing before an advisory committee. The specific provisions are—

(i) Section 14.120 on review of a performance standard for an electronic product by the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC);

(ii) Section 14.140 on review of the safety of color additives;

(iii) Section 14.160 on review of the safety and effectiveness of human prescription drugs;

(iv) Section 330.10 on review of the safety and effectiveness of over-the-counter drugs;

(v) Section 60[illegible] on review of the safety and effectiveness of biological drugs;

(vi) Part 860, on classification of devices;

(vii) Section 514(g)(5) of the act on establishment, amendment, or revocation of a device performance standard;

(viii) Section 515 of the act on review of device premarket approval applications and product development protocols; and

(ix) Section 520(l) of the act on review of device good manufacturing practice regulations.

(3) A person who has a right to an opportunity for a formal evidentiary public hearing under Part 12 waives that opportunity and instead under § 12.32 requests a hearing before an advisory committee, and the Commissioner, as a matter of discretion, accepts the request.

(b) In determining whether a group is a "public advisory committee" as defined in § 10.3(a)(14) and thus subject to this part and to the Federal Advisory Committee Act, the following guidelines will be used:

(1) An advisory committee may be a standing advisory committee or an ad hoc advisory committee. All standing advisory committees are listed in § 14.100.

(2) An advisory committee may be a policy advisory committee or a technical advisory committee. A policy advisory committee advises on broad and general matters. A technical advisory committee advises on specific technical or scientific issues, which may relate to regulatory decisions before FDA.

(3) An advisory committee includes any of its subgroups when the subgroup is working on behalf of the committee. Section 14.40(d) describes when a subgroup will be established as an advisory committee separate from the parent committee.

(4) A committee composed entirely of full-time Federal Government employees is not an advisory committee.

(5) An advisory committee ordinarily has a fixed membership, a defined purpose of providing advice to the agency on a particular subject, regular or periodic meetings, and an organizational structure, for example, a chairman and staff, and serves as a source of independent expertise and advice rather than as a representative of or advocate for any particular interest. The following groups are not advisory committees:

(i) A group of persons convened on an ad hoc basis to discuss a matter of current interest to FDA, but which has no continuing function or organization and does not involve substantial special preparation.

(ii) A group of two or more FDA consultants meeting with the agency on an ad hoc basis.

(iii) A group of experts who are employed by a private company or a

NATIONAL CENTER FOR DRUGS AND BIOLOGICS

OFFICE OF BIOLOGICS RESEARCH AND REVIEW

November 10, 1983
NIH, Building 29, Room 121
Pertussis Vaccine: Status of Current Research

9:00	Introduction	Paul D. Parkman, M.D.
9:15	Overview of Current Pertussis Research and Vaccine Development	M. Carolyn Hardegree, M.D.
9:30	Discussion	
10:00	Coffee	
10:30	Discussion of Pertussis Vaccine Reaction Studies	Kenneth Bart, M.D.
11:30	Recent U.S. Studies of Pertussis Vaccine	John C. Petricciani, M.D.
	Review of Baraff Unsolicited Proposal and Discussion of Approaches to Follow-up Evaluation	David L. Klein, M.D.
12:00	Lunch	
1:00	Current Adverse Reaction Follow-up Systems MSIFI	Harrison Stetler, M.D.
	FDA Adverse Reaction Reporting System	Gerald Faich, M.D.
2:00	Discussion	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Bethesda MD 20205

MAR 06 1984

Larry J. Baraff, M.D.
Emergency Medicine
UCLA Center for the Health Sciences
Los Angeles, CA 90024

Dear Dr. Baraff:

This is in response to your unsolicited proposal to the National Institutes of Allergy and Infectious Diseases entitled "Followup Evaluation of the Nature and Rates of Adverse Reactions Associated with DTP Vaccination: Neurologic and Psychometric Evaluation and Tissue Typing of Infants and Children with More Serious Reaction."

Since the study you proposed included the follow-up of subjects who participated in a study funded by the Food and Drug Administrating during the period 1977 to 1979, and because the Centers for Disease Control is interested in pertussis, we elected to review the proposal jointly with an ad hoc group of consultants in the context of a more general meeting on pertussis vaccine.

The participants concluded that it was improbable that statistically valid information would be obtained concerning either residual neurological disease or the possible relationship of HLA type to adverse reactions. In addition to the problem posed by the small number of subjects, data for some of the parameters such as neurologic and psychometric evaluations would be extremely difficult to interpret in the strict scientific sense because of the problem common to studies of this type, the lack of comparable baseline data for study subjects. Again, given the small number of participants in the study, there is very low probability of detecting any HLA associations. Experience with other diseases has shown that a strong familial history of a condition is usually observed if HLA typing is to demonstrate any association with disease. Current information does not suggest a strong familial association with pertussis reactions. Interpretation of HLA results would be further confounded by the observation that there are two distinct subsets of adverse events, convulsive reactions and collapse reactions (hypotonic/hyporesponsive).

Because of the small number of subjects in the proposal, it was suggested that if you still wanted to pursue HLA studies on the 18 children, you may want to independently consider this matter with Dr. Terasaki at UCLA to inquire whether or not he would be willing to do the assays for you.

We agree with the group's view that the proposed study should not be funded. However, we also believe that the argument can be made that medical and neurological follow-up of the 13 children is reasonable as a matter of medical care. We would therefore be willing to explore with you providing funds for assessment of the current general medical and neurological status of as many of the 13 children as can be located. We will be in contact with you and Dr. Cherry about this is in the near future.

Sincerely yours,

William S. Jordan, M.D.
Director, Microbiology and
Infectious Diseases Program
NIAID

Paul D. Parkman, M.D.
Scientific Director
National Center for Drugs and Biologics

Memorandum of Telephone Conversation
on May 11, 1984 between
Drs. James Cherry, Paul Parkman and William Jordan

Subject: Followup on children participating in Baraff DPT study.

Dr. Jordan and I contacted Dr. Cherry as a followup to our March 6 letter to him regarding this study. We discussed with him his thinking about the issues raised in our letter. He said that he felt that some sort of plan for contacting and examining the 19 study participants who had experienced adverse reactions (seizures, "shock-like" episodes) seemed reasonable. He said that he would gather his thoughts on the matter and would get back to us in the near future.

Paul D. Parkman
Paul D. Parkmanm, M.D.

cc: Dr. William Jordan
Dr. Carolyn Hardegree

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

June 27, 1984

Dr. James Cherry
University of California
School of Medicine
Department of Pediatrics
Center for the Health Sciences
Los Angeles, CA 90024

Dear ~~Dr. Cherry~~ Jim:

This is a brief note concerning the DTP followup matter; I wanted to be sure we haven't missed connection while I was on vacation. Let us know if we can be helpful to you.

Sincerely yours,

Paul

Paul D. Parkman, M.D.
Scientific Director
Center for Drugs and Biologics

cc: Dr. William Jordan

CONVERSATION RECORD

DATE: 7/17/84

TIME: AM PM

CHECK ONE: ☒ INCOMING ☐ OUTGOING ☐ MEETING

CIRCULATION:
Dr. Esber
Dr. Jordan
Dr. Hinman
Dr. Hardegree

BUREAU OF BIOLOGICS REPRESENTATIVE: Paul D. Parkman, M.D., Scientific Dir., CDB

ORGANIZATION REPRESENTATIVE: Dr. Larry Baraff, UCLA

TELEPHONE NO.:

ORGANIZATION: UCLA

SUBJECT: Followup of Subjects Involved in DTP Vaccine Study

TEXT	ACTION REQUIRED
Dr. Baraff called today and talked with Dr. Esber and myself to indicate that he was interested in contacting the parents of the 18 children who experienced adverse reactions (seizures and "shock-like" episodes) following immunization in his and Dr. Cherry's study. He indicated that he would be sending us a letter outlining his ideas concerning how this might be done. He estimates that at least half of the participants will be relatively easy but that at least some may be more difficult to locate. He said he would send a letter giving more details of his proposal.	

FORM FDH 2574 (10/73) OVERPRINT NO. 1

Senator HAWKINS. So, if I were to summarize the current status of the development of a safer pertussis vaccine, I could make a list saying, No. 1, you awarded a grant to Michigan Department of Health and Biologics to develop an acellular vaccine; is that right?

Dr. BRANDT. That is correct.

Senator HAWKINS. When would those lots be available for testing?

Dr. HINMAN. Probably not for another year or more.

Senator HAWKINS. 1985? 1986?

Dr. HINMAN. I cannot give you an exact date at the moment, Madam Chairman. We can submit a best estimate for you, if you would like.

[Material supplied follows:]

ADDITIONAL INFORMATION SUPPLIED BY DR. HINMAN

The contract with the Michigan Department of Public Health was awarded for three years with the intent of developing a new candidate acellular vaccine for pertussis. The project consists of two phases: (1) development and testing of an acellular pertussis vaccine; and (2) the preparation of an aluminum adsorbed DTP vaccine using the acellular pertussis vaccine as the "P" component. Work officially began on the project on September 1, 1983. For the past ten months the contractor has been examining various factors which might enhance cell growth and biosynthesis of two chemical components of the cell walls of the pertussis bacterium involved in the production of a protective immune response (i.e. production of protective antibodies). The efforts have now reached a point where the cell fractions have been isolated from the culture fluid, partially purified on columns, and are now being examined and characterized for purity and biological activity.

The isolation and purification of the protective cell wall component is a very labor intensive and difficult task to perform requiring a great deal of skill and a certain amount of good fortune. Because this approach to pertussis vaccine development is new, there are a number of technical problems associated with it, which still need to be resolved. Therefore, it would be very difficult, at this time, to predict exactly when the vaccine will be available for clinical testing. However, barring unforeseen technical difficulties and based on the current status and progress of the contractor, it is possible that clinical studies could begin as soon as the Fall of 1986.

Senator HAWKINS. Once they are available for testing, then how long does it take after that to have them available to the public?

Dr. HINMAN. After that, it takes quite a while, also. If I could just explain, for example, the NIH has vaccine evaluation centers at Marshall University in West Virginia and Vanderbilt University in Nashville which are presently ready to administer improved pertussis vaccines to children under controlled clinical conditions. It seems likely that improved vaccines from commercial manufacturers may be submitted first for testing before the contract at Michigan reaches fruition.

But even after this limited clinical testing to establish initial seroconversion response and safety, there will be larger scale field trials required to demonstrate efficacy. One problem with this is that the incidence of pertussis is, fortunately, low enough in this country that in order to have a large-scale trial to demonstrate efficacy, we would have to have a very large-scale trial. It is likely that field trials to demonstrate efficacy will have to be undertaken in another country.

Senator HAWKINS. Undertaken in another country?

Dr. HINMAN. That is correct.

Senator HAWKINS. And we will accept that data?

Dr. HINMAN. Yes, Madam; if these are carried out under protocols approved in the United States.

Senator HAWKINS. Well, then, why can't we accept the Japanese vaccine which is proven to be safe?

Dr. HINMAN. We have not received data to indicate the efficacy from the Japanese.

Senator HAWKINS. I went to Japan after one of these hearings and I talked to the Minister of Health and asked if we could test his vaccine, and he said no one had ever requested to test the vaccine; he would be more than happy to provide it.

Now I understand that Wyeth Laboratories is testing it for safety. Are those under your protocols, the testing they are doing?

Dr. HINMAN. That is being done toward development of an investigational new drug which would allow, then, clinical testing in the centers funded by the NIH.

Senator HAWKINS. Which would be shorter, for us to wait for the Michigan Department of Health vaccine, which you say may be years and years, or for us to test the Japanese vaccine, which may require testing outside of the country?

Dr. HINMAN. So will the Wyeth product most probably.

Dr. BRANDT. The difficulty, Madam Chairman, is that there are so few cases of pertussis in this country that it is very difficult to evaluate the efficacy of a preventative if, in fact, the disease rarely occurs anyway, since most children are already immunized. Therefore, it would require us, under either circumstance, to go outside. Our own view is that both efforts should proceed.

Senator HAWKINS. You should be testing the Japanese vaccine out of the country?

Dr. BRANDT. Yes.

Senator HAWKINS. Why can't we accept the Japanese data?

Dr. BRANDT. It assumes that they have it. I am sure that Wyeth——

Senator HAWKINS. They're very clever.

Dr. BRANDT. I am well aware of that, yes, Madam. I know that. I am sure that so is Wyeth, as a matter of fact. [Laughter.]

I am sure that if Wyeth were satisfied or otherwise, that that would already have been accepted and utilized.

As you know, up until now we have had fairly strict regulations concerning foreign data, but we are in fact—we have reexamined that and use it a great deal more.

If you would like, I will try to get an up-to-date status report on the Wyeth situation and send it to you.

Senator HAWKINS. Thank you. I would appreciate that for this record.

[Material supplied follows:]

STATUS REPORT: TESTING OF JAPANESE PERTUSSIS VACCINE

Wyeth Laboratories and the National Institute of Allergy and Infectious Diseases, NIH are participating in the studies of an experimental Diphtheria and Tetanus Toxoid and Pertussis (DPT) vaccine.

The vaccine, prepared by Wyeth, incorporates a Japanese acellular pertussis component. Thus far small experimental batches have been made available and clinical trials of the preparation are currently in progress. Children are being immunized, starting with 4 to 6 year olds; this portion of these trails is currently in progress. These studies will eventually involve progressively younger subjects, eventually encompassing the entire primary immunization series in infants, the vaccine beging given in accordance with current recommendations at 2, 4, 6 and 18 months.

Senator HAWKINS. Dr. Mason, we don't mean to neglect you. The CDC has funded a study to evaluate the effectiveness of a three-dose rather than the current fourdose of pertussis vaccine. If that proves to be effective, do you think it might reduce adverse reactions?

Dr. MASON. That is one of the reasons we are doing the study: first of all, to make sure that the efficacy of the vaccine will not be lowered in the process of reducing the number of vaccinations that are necessary; and, secondly, to find out whether there are fewer adverse reactions. The study is not completed, but I would think we would have it in another 2 years.

Senator HAWKINS. Two years? But if it were successful, it may reduce the adverse reactions by as much as 20 percent?

Dr. MASON. We would hope so, but we don't have the data yet. That is what we are trying to determine.

Senator HAWKINS. I understand that the Public Health Service Immunization Practices Advisory Committee, which is a mouthful, has reviewed the data regarding the relationship between the history of febrile and nonfebrile convulsions and the risk of adverse reactions following vaccination. Has this review prompted any reconsideration of the contraindications for vaccine?

Dr. BRANDT. Yes, Madam; for the DTP vaccination, we published on April 6, 1984, in "the Morbidity and Mortality Weekly Report" a supplementary statement on the contraindications to the receipt of pertussis. We would be pleased to submit a copy of that for the record.

Senator HAWKINS. Yes; I would like that, please.

[Material supplied follows:]

CENTERS FOR DISEASE CONTROL

MMWR

MORBIDITY AND MORTALITY WEEKLY REPORT

April 6, 1984 / Vol. 33 / No. 13

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Recommendation of the Immunization Practices Advisory Committee (ACIP)

Supplementary Statement of Contraindications to Receipt of Pertussis Vaccine

The following statement updates some of the previous recommendations regarding pertussis vaccine (1). *The Immunization Practices Advisory Committee (ACIP) reviewed the available data concerning the risks of pertussis disease and pertussis vaccine to infants and children with personal or family histories of convulsions. Based on available evidence, the ACIP does not consider a family history of convulsion to be a contraindication to receipt of pertussis vaccine. However, a personal history of a prior convulsion should be evaluated before initiating or continuing immunization with vaccines containing a pertussis component (i.e., diphtheria and tetanus toxoids with pertussis vaccine [DTP]) (Table 1).*

DEFERRAL OF DTP FOR INFANTS AND CHILDREN WITH PERSONAL HISTORIES OF CONVULSION(S)

Although there are uncertainties in the reported studies, recent data suggest that infants and young children who have previously had convulsions (whether febrile or nonfebrile) are more likely to have seizures following pertussis vaccination than those without such histories (*2*). Available data do not indicate that seizures temporally associated with vaccine administration predispose to permanent brain damage or exacerbate existing conditions. The incidence of pertussis in most areas of the United States is presently quite low. Consequently, for infants and young children who have histories of seizures before initiation of DTP immunization or who develop seizures before the four-dose primary series is completed, initiating or continuing pertussis immunization should be deferred until it can be determined that there is not an evolving neurologic disorder present. If such disorders are found, the infants or children should be given diphtheria and tetanus toxoids (DT) instead of DTP. If DT is used, three doses at least 4 weeks apart, followed by a fourth dose 6-12 months later, are recommended for infants. For children 1 year of age or older, two doses of DT at least 4 weeks apart, followed by a third dose 6-12 months later, are recommended.

RECOMMENDATIONS FOR BEGINNING OR CONTINUING DTP AFTER DEFERRAL

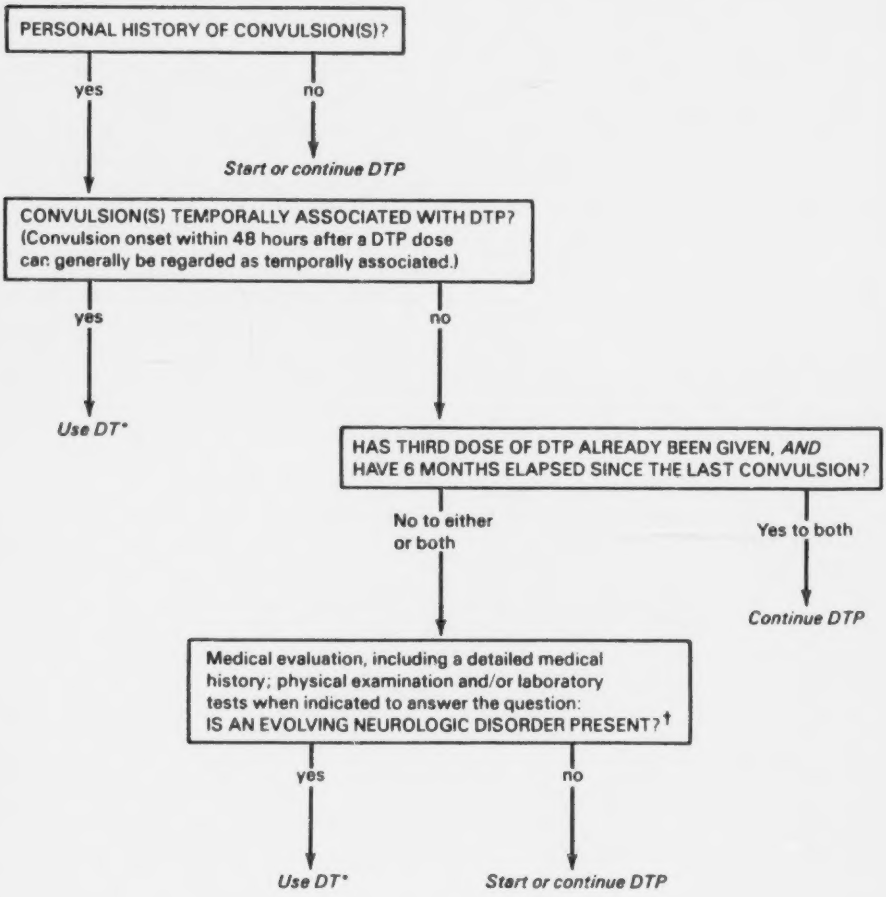
For infants and children whose DTP immunizations are deferred because of histories of convulsion(s), the decision whether to proceed with DTP immunization can usually be made within the next few months. For infants who have received fewer than three doses of DTP, such a decision in most instances should be made no later than at 1 year of age. Following individual assessment, it may be decided to proceed with DTP, because infants and young children with convulsive disorders also appear to be at higher risk of adverse outcomes if they contract pertussis disease. Further, if unimmunized infants attend day-care centers, special clinics, and residential-care settings where other children may be unimmunized or if they

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES / PUBLIC HEALTH SERVICE

Pertussis Vaccine — Continued

TABLE 1. Guidelines for diphtheria-tetanus-pertussis (DTP) immunization of infants and young children with histories of convulsion(s)

The following general guidelines cannot cover every situation. Individualized medical judgment in specific cases may indicate a different course of action.


PERSONAL HISTORY OF CONVULSION(S)?
yes
no
Start or continue DTP
CONVULSION(S) TEMPORALLY ASSOCIATED WITH DTP? (Convulsion onset within 48 hours after a DTP dose can generally be regarded as temporally associated.)
yes
no
*Use DT**
HAS THIRD DOSE OF DTP ALREADY BEEN GIVEN, *AND* HAVE 6 MONTHS ELAPSED SINCE THE LAST CONVULSION?
No to either or both
Yes to both
Continue DTP
Medical evaluation, including a detailed medical history; physical examination and/or laboratory tests when indicated to answer the question: IS AN EVOLVING NEUROLOGIC DISORDER PRESENT?†
yes
no
*Use DT**
Start or continue DTP

---

*For infants and children who received diphtheria-tetanus (DT), but who, on further evaluation, can be given pertussis vaccine, a separate pertussis vaccine is available. It is distributed by the Michigan State Department of Public Health.

†If the presence or absence of an evolving neurologic disorder cannot be established within 6 months after deferral of DTP, DT should be given rather than further delaying immunization.

Pertussis Vaccine — Continued

travel to or reside in areas where the disease is endemic, they may be at increased risk of exposure to pertussis.

For infants and children with stable neurologic conditions, including well-controlled seizures, the benefits of pertussis immunization outweigh the risks, and such children may be vaccinated. The occurrence of single seizures (temporally unassociated with DTP) in infants and young children, while necessitating evaluation, need not contraindicate DTP immunization, particularly if the seizures can be satisfactorily explained. An example might be a febrile seizure in the course of exanthem subitum in a 14-month-old child. As with all infants or children with one or more febrile seizures, consideration of continuous anticonvulsant prophylaxis may be warranted.

Parents should be fully informed of the benefits and risks of immunization with DTP. Parents of infants and children with histories of convulsions should particularly be made aware of the slightly increased chance of post-immunization seizures. A minimum of three doses of DTP given at intervals of at least 4 weeks is necessary to provide adequate protection against pertussis. A fourth dose 6-12 months later is also recommended.

CONTRAINDICATIONS TO PERTUSSIS VACCINE

Hypersensitivity to vaccine components, presence of an evolving neurologic disorder, or a history of a severe reaction (usually within 48 hours) following a previous dose all remain definitive contraindications to the receipt of pertussis vaccine. Severe reactions include collapse or shock, persistent screaming episode, temperature 40.5 C (105 F) or greater, convulsion(s) with or without accompanying fever, severe alterations of consciousness, generalized and/or local neurologic signs, or systemic allergic reactions. Although hemolytic anemia and thrombocytopenic purpura have previously been considered contraindications by the ACIP, the evidence of a causal link between these conditions and pertussis vaccination is not sufficient to retain them as contraindications.

OTHER IMMUNIZATIONS FOR INFANTS AND CHILDREN FOR WHOM PERTUSSIS VACCINE IS CONTRAINDICATED

Immunization with DT and/or oral polio vaccine is not known to be associated with an increased risk of convulsions. Therefore, a history of prior convulsions is not a contraindication to receipt of these toxoids and vaccine. In addition, a history of prior convulsion(s) is not a contraindication for measles-mumps-rubella (MMR) vaccine. Further details concerning DTP vaccine or DT toxoids can be found in the 1981 ACIP statement (*1*).

References

1. ACIP. Diphtheria, tetanus, and pertussis: guidelines for vaccine prophylaxis and other preventive measures. MMWR 1981;30:392-6, 401-7.
2. CDC. Adverse events following immunization. Surveillance Report No. 1, 1979-1982 (in press).

Epidemiologic Notes and Reports

Isotretinoin — A Newly Recognized Human Teratogen

Isotretinoin (Accutane®), an orally administered, retinoic acid licensed in September 1982 for treating severe, intractable cystic acne, has been associated with spontaneous abortions and congenital malformations. The manufacturer (Roche Laboratories) and the U.S. Food and Drug Administration (FDA) have received 29 case reports of adverse reproductive outcomes among women taking isotretinoin (Accutane) during the first trimester of pregnancy.

Senator **Hawkins**. I have several questions that I will just submit to you at this time for the record. You may have to consult the Justice Department on some of them when you give us an answer, because I am concerned with your final statement that you are not convinced that the Federal program is needed to resolve the situation and that you oppose this bill.

Does that mean you are completely satisfied with what we have?

Dr. **Brandt**. Well, no; we're not completely satisfied with what we have, Madam Chairman. I think the real issue is how to go about structuring a system that is fair and that at the same time is clearly based upon good, solid, clinical, and scientific evidence of adverse effects that are clearly associated with vaccines. I think that at this point in time we are trying to determine what is the most effective system.

The reason that statement is in there is that we have examples of no-fault-type systems that are maintained in the private sector by insurance companies and others, and the question really in part is whether or not that system works, and do we need Federal legislation to accomplish it or can it be done within current authorities? Those are legal questions. As you point out, the Department of Justice will have to speak to that.

I think the concept of the bill is certainly one that I like and think is important. I think that you should be commended for raising this situation because it is very, very clear that all of us are aware that every vaccine is not 100 percent safe, in the sense that there are children who still experience problems with them. It does seem reasonable that some sort of system to assist in the care of those children be set up. I guess the real question is, what is the most effective way to accomplish that?

Senator **Hawkins**. Is it still true that 30 to 50 percent of the vaccines are purchased through the Federal Government?

Dr. **Hinman**. That is correct.

Senator **Hawkins**. Shouldn't the Federal Government have some responsibility in the distribution of this vaccine?

Dr. **Brandt**. I think we do have some responsibility certainly for informing people and for providing information, in doing the sorts of things that we are trying to do at the present time.

Whether a system such as this needs to be a Federal system or whether it can be a private system, working through the established insurance industry and manufacturers, I guess, is more of a legal question than I am competent to deal with.

Senator **Hawkins**. But you do support the concept?

Dr. **Brandt**. I personally think the concept is important, yes.

Senator **Hawkins**. I appreciate that you have been willing to work with us to try to develop a solution to the problems that were raised in these four hearings. We have worked very closely with the American Academy of Pediatrics, who really feel they have assumed already too much private responsibility for a mandated program. I am sure that if we all work together that we can help the children, who are the ones who are really injured by this.

We appreciate your coming here today. I know you are busy, gentlemen. I work with you on so many other projects, and I appreciate your cooperativeness in working with us to solve this problem.

Dr. **Brandt**. Thank you very much.

Senator HAWKINS. Maybe we can convince you to support the bill.

Our next panel is composed of parents and grandparents who are very concerned about the childhood immunization program and who have been very active in seeking improvements in our Nation's childhood immunization program. These witnesses are Jeff Schwartz, who represents the Dissatisfied Parents Together; Donna Gary, from Wayland, MA; and Stephen Kudabeck, of Little Rock, AR.

Jeff, since you played such a pivotal role in helping develop this legislation, would you start, please?

STATEMENT OF JEFFREY H. SCHWARTZ, REPRESENTING DISSATISFIED PARENTS TOGETHER

Mr. SCHWARTZ. Thank you, Senator Hawkins. I appreciate the opportunity to appear before you today and to represent Dissatisfied Parents Together [DPT]. We are a group who sees as its primary responsibility the education of parents and, working with doctors, the education of physicians and public health authorities as to the need to be concerned about the pertussis vaccine's safety as well as about pertussis disease.

In the testimony which follows we would like to cover four main points. First, we want to review the reasons why we believe that a bill like S. 2117 is needed, contrary to the HHS testimony. Second, we want to recall the 10 principles which we presented before you at the last hearing that we thought ought to be used as a guide for judging what is a genuine and acceptable vaccine victim compensation bill. Third, we would like to assess how S. 2117 measures up to these 10 principles. Fourth, we would like to identify some key issues and concerns regarding the bill, briefly closing with a few final remarks.

In terms of the need for a bill like S. 1227, at the outset we particularly want to thank Senator Hawkins and Chairman Hatch and the other cosponsors of S. 2117 for their leadership in bringing the issue of vaccine safety to national attention.

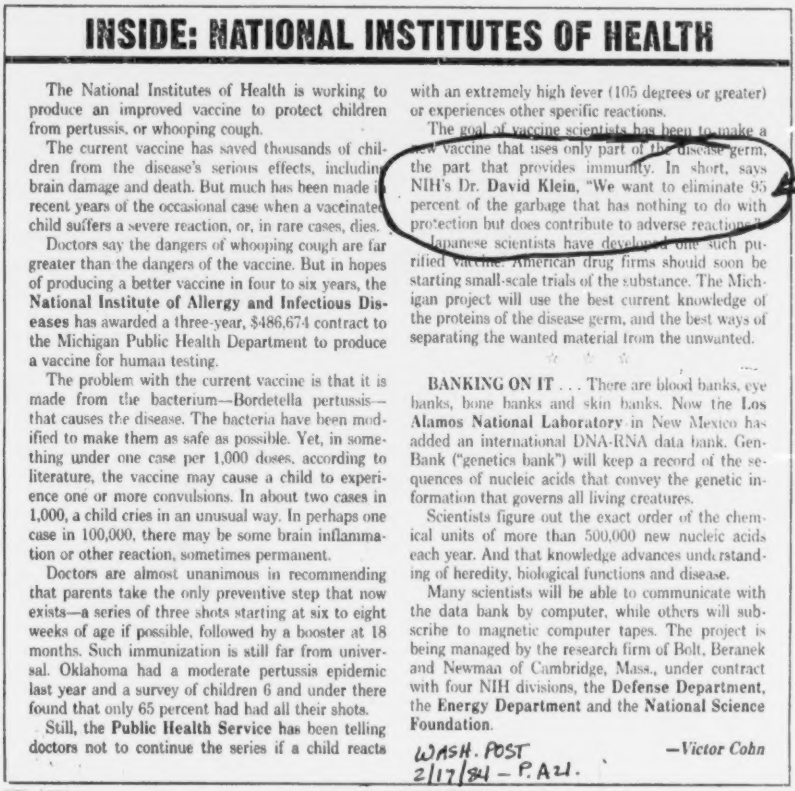
This committee's hearing on May 7, 1982 and July 22, 1983 helped demonstrate the need for national legislation such as S. 2117. The record developed in those hearings is an important part of the background of this bill, and any attempt to evaluate the bill has to begin with a review of the findings which emerged from those hearings and the materials contained in them.

The hearings provided a basis for several findings:

Finding No. 1 is that pertussis vaccine—the "P" part of the present DPT vaccine—is a relatively crude, impure, reactive vaccine of unquestioned toxicity and uncertain character.

Now it is disturbing to hear HHS say that the pertussis vaccine is safe, although not perfectly safe. It is disturbing because one of HHS's own doctors who is involved in this was quoted recently in The Washington Post saying, "We want to eliminate 95 percent of the garbage that has nothing to do with protection but does contribute to adverse reactions." Garbage in the vaccine—that is an outspoken way of saying it, but I think when you look at the HHS testimony, as I hope we will have a chance to do more closely, you will find very disturbing shading of the meanings of language used there. We would like to submit the Washington Post article for the record.

[The article referred to follows:]



INSIDE: NATIONAL INSTITUTES OF HEALTH

The National Institutes of Health is working to produce an improved vaccine to protect children from pertussis, or whooping cough.

The current vaccine has saved thousands of children from the disease's serious effects, including brain damage and death. But much has been made in recent years of the occasional case when a vaccinated child suffers a severe reaction, or, in rare cases, dies.

Doctors say the dangers of whooping cough are far greater than the dangers of the vaccine. But in hopes of producing a better vaccine in four to six years, the **National Institute of Allergy and Infectious Diseases** has awarded a three-year, $486,674 contract to the Michigan Public Health Department to produce a vaccine for human testing.

The problem with the current vaccine is that it is made from the bacterium—Bordetella pertussis—that causes the disease. The bacteria have been modified to make them as safe as possible. Yet, in something under one case per 1,000 doses, according to literature, the vaccine may cause a child to experience one or more convulsions. In about two cases in 1,000, a child cries in an unusual way. In perhaps one case in 100,000, there may be some brain inflammation or other reaction, sometimes permanent.

Doctors are almost unanimous in recommending that parents take the only preventive step that now exists—a series of three shots starting at six to eight weeks of age if possible, followed by a booster at 18 months. Such immunization is still far from universal. Oklahoma had a moderate pertussis epidemic last year and a survey of children 6 and under there found that only 65 percent had had all their shots.

Still, the **Public Health Service** has been telling doctors not to continue the series if a child reacts with an extremely high fever (105 degrees or greater) or experiences other specific reactions.

The goal of vaccine scientists has been to make a new vaccine that uses only part of the disease germ, the part that provides immunity. In short, says NIH's Dr. **David Klein**, "We want to eliminate 95 percent of the garbage that has nothing to do with protection but does contribute to adverse reactions."

Japanese scientists have developed one such purified vaccine. American drug firms should soon be starting small-scale trials of the substance. The Michigan project will use the best current knowledge of the proteins of the disease germ, and the best ways of separating the wanted material from the unwanted.

* * *

BANKING ON IT . . . There are blood banks, eye banks, bone banks and skin banks. Now the **Los Alamos National Laboratory** in New Mexico has added an international DNA-RNA data bank. GenBank ("genetics bank") will keep a record of the sequences of nucleic acids that convey the genetic information that governs all living creatures.

Scientists figure out the exact order of the chemical units of more than 500,000 new nucleic acids each year. And that knowledge advances understanding of heredity, biological functions and disease.

Many scientists will be able to communicate with the data bank by computer, while others will subscribe to magnetic computer tapes. The project is being managed by the research firm of Bolt, Beranek and Newman of Cambridge, Mass., under contract with four NIH divisions, the **Defense Department**, the **Energy Department** and the **National Science Foundation**.

—Victor Cohn

WASH. POST
2/17/84 – P. A21.

Mr. SCHWARTZ. I think it is important to emphasize that statements about the pertussis vaccine being crude and of unquestioned toxicity, come from leading proponents of the vaccine, such as Dr. Mortimer.

Finding No. 2, since Madsen's 1933 study, more than 50 years ago, it has been know that whole cell pertussis vaccines can cause high fevers; convulsion; anaphylactic shock; epilepsy; brain damage; mental retardation; paralysis; loss of hearing, sight and speech; and even death. We are not saying that all those things are caused only by pertussis vaccine, but those things can be caused by pertussis vaccine. That is demonstrated in 50 years of published medical literature.

Finding No. 3, the vast majority of practicing physicians and public health clinics in the United States have until very recently either been uninformed of these facts or unwilling to admit them. Generally agreedupon contraindications to administration of the vaccine have been ignored all too frequently, with tragic resulting consequences. The contraindications which have been set out by the quasi-official bodies like ACIP and the AAP have been far too narrow. This is particularly troublesome as the vaccine system has become more and more compulsory.

Physicians have failed to keep adequate records and make adequate reports of severe vaccine reactions. Perhaps most damning of all, physicians have failed to inform their patients and listen to them about vaccine dangers and reactions. Physicians have thus deprived us parents of the information we need to protect our children and deprived themselves of critical knowledge about what is really going on with their patients, so that they can treat them well. I don't mean to indict all physicians, but it is a sad fact that what is known at the highest levels of the American Academy of Pediatrics and the American Medical Association and HHS has not made its way to the rank and file. Adequate safeguards are not being implemented in current practice.

Finding No. 4, physicians have tended to rely on the belief that the Government would not license, and pharmaceutical manufacturers would not sell, an unsafe vaccine to children. The doctors have tended to assume that whole cell pertussis vaccine had been proven thoroughly safe and effective, and they have been told by HHS that the vaccine is safe and effective. In testimony before you HHS has said the vaccine has been proven safe and effective, and yet we continue to have these severe reactions.

Doctors have assumed that the vaccines have been adequately tested and screened; that they have been manufactured with careful quality control; properly labeled, stored, and shipped according to specification; that they included adequate warnings, and were subject to adequate postmarket surveillance.

Even more important, universal legal requirements for pertussis vaccination have led most U.S. physicians to conclude that they no longer need to exercise individual judgment in deciding on a case-by-case basis whether, when, and under what circumstances to vaccinate children with DPT vaccine. These legal requirements have led to relaxation of physician vigilance, scrapping of the doctrine of informed consent, and incursion on a parent's first and most fundamental freedom—the freedom to protect the health and well-being of our children.

Finding No. 5, the Health and Human Services Department has performed woefully and inadequately to protect the health of our children in this area. It has failed for over 40 years to push for a vaccine safer than the whole cell pertussis vaccine. It has not provided an adequate regulatory framework to assure that whole cell vaccines are made and administered as safely as possible. HHS sees its function as licensing, not regulating vaccine; the Department has not assumed responsibility for development of safer vaccines. For years HHS has studied the need for compensating children who are severely injured by vaccines, yet the Department has not put forth a single proposal. They have been working on the compensation issue for more than 7 years, and yet HHS comes here today to say they are in favor of the concept, but they are just against its implementation. They say they don't think Federal legislation is needed, and they do not have any proposals of their own to present after 7 years. How long do we have to wait for them to come up with a program that meets the need and the responsibility that they have implicitly acknowledged here?

The Health and Human Services Department has strongly encouraged State laws mandating vaccination as a precondition for school entry, yet has failed to acknowledge the need for flexibility and sensitivity in the vaccination system. The Department has kept vaccine public policymaking in the hands of the few and out of sight of the many. It has not insisted on adequate accountability by doctors and vaccine makers and HHS has not been willing to be accountable itself. Perhaps worst of all, the Department has by and large refused to get the facts, know the facts, and share the facts with the public, or even acknowledge the facts that they have got.

Finding No. 6, in the face of these realizations over the last 2 years, parents have had to turn to the courts, to the Congress, and ultimately to ourselves, to redress these grievances. That is why Dissatisfied Parents Together came into being. That is why we developed our own parent information packet: because the doctors have not done it for us, because Health and Human Services Department has not done it for us, because the manufacturers have not made it available to parents. That is why increasing numbers of lawsuits are being filed on behalf of vaccine-damaged children, because there is no alternative for those children. That is why a bill like S. 2117 is needed.

Finding No. 7, there is a middle ground for better protecting our children's health. We need not be blind to the dangers of pertussis vaccine in order to be concerned about the dangers of whooping cough; but we need not ignore concerns about whooping cough in order to avoid vaccine-related brain damage. Parents are not going to freak out if we talk about these problems carefully and thoughtfully. Parents are not going to go nuts about this. We are concerned about the health of our children, and we want to find a way that is a middle ground. Being concerned about both the disease and the vaccine, we can work in an informed and balanced way to safeguard our children's health from both the risks of the disease and of the currently available vaccine.

The next section of my testimony talks about the 10 principles that we listed in previous testimony for what we thought would be a good bill. These principles were set forth before the bill was developed, and I won't restate those. They are listed in my testimony from last time, and we will put them in this record.

Suffice it to say, the important part about the principles was that DPT felt from the very beginning we could not support a bill that simply compensated children who are injured; that did not provide a strong mandate for the creation of safer vaccines, for the use of safer vaccines, for the implementation of a safer system for using the current vaccine. We would not agree to sweep the problem under the rug by paying off the families and the children who are damaged and let this process of administering a hazardous vaccine go on without challenge.

This is one of the reasons why we are so pleased with S. 2117. S. 2117 is not merely a compensation bill. It is a health bill and the bill sets forth specific requirements to assure that HHS assumes its proper responsibility; that doctors assume their proper responsibility; that manufacturers assume their responsibility; and that we parents have the information available to assume our responsibility.

We believe S. 2117 meets all 10 of the principles that we have previously prescribed and, thus, Dissatisfied Parents Together does support enactment of S. 2117. We do not say this without some reservations or concerns, however, and we want to discuss these concerns briefly at the end. Before doing so, however, we do want to highlight several key points about the strengths of the bill.

As I pointed out, we are very pleased about parts C and D of the bill because these provisions do create statutory mandates for development and use of safer vaccines, and for strengthening the current system to prevent serious vaccine reactions. These are not mere grants of authority. HHS has had much of the authority it needs to properly protect the public but the Department has not used its authority adequately. Thus, the bill, S. 2117, creates a nondiscretionary duty, in fact, a set of duties, that the Secretary will have to carry out to assure that the parents get the information, that vaccine serious reactions are recorded and reported, that a safer vaccine is developed and used, and to incorporate safeguards in the current vaccine system to assure that children are protected.

If the Secretary of HHS fails to use any authority she has under any existing law or fails to implement this law to carry out these mandates, a citizen suit could be filed and the courts would mandamus the Secretary to act. The record is clear as to why this is needed; the record is painfully clear.

Likewise, these parts of the bill mandate certain safeguards to be carried out by the doctors and the health care providers. The new duties would become part of a physician's standards of practice or care. Any failure to carry out these mandates, to make the required information available to parents, to keep the records, to make the reports, to abide by contraindications, would at least create a presumption of negligence, perhaps even constitute negligence per se. A pattern of refusal or failure to implement the law could lead to punitive damages under tort law or be considered in licensure review proceedings. We are pleased to note that—and I think this is something that Senator Hawkins is entitled to take some credit for, and I think it is a wave of the future—we are pleased to note that the State legislature of Maryland has become the first State to pass legislation based on part C and part D of this bill. I think there are many more States to follow. Again, national leadership is needed.

In the Maryland State Legislature, interestingly, we said victim compensation is a key element, and the State legislators said to us, "We sympathize with you, but that's a national problem. You have to go to the Congress." That is what our State legislators told us in Maryland, and that is what we are finding throughout the country.

Adequate compensation is not going to be done by the private insurance system; it hasn't been. It is not going to be done by the States. It is not going to be done by HHS. It is up to the Congress to enact legislation to protect the children who in the past and the future are injured by these vaccines.

We also want to point out the importance of the procedural and judicial review provisions of S. 2117. The vaccine licensure process and vaccine policy processes have not been open to the public. Parent input has not only not been solicited by the AAP or ACIP or the States; when offered, parent input has frequently been totally ignored. The presently closed system needs to be open and accountable, and these provisions for procedural openness and judicial review will help produce healthier children and a better system.

Without parts C and D of the bill, DPT could not support it. We think these provisions are critical, and we think they deserve special appreciation and attention. It is too bad that the Health Department did not see fit to address those parts of the bill. I think, if they had, they would have said, as they have told us previously in correspondence, that they could not support these other provisions, either.

Compensation without prevention would sweep the problem under the rug. We think there is a serious problem and it needs to be dealt with. If there is one question in this hearing that we would like the committee to consider, it is, Is there a problem and does it need to be dealt with?

If I heard HHS right, they said either there isn't a problem, or there is but it doesn't need to be dealt with, or it does need to be dealt with but not by us, or give us 7 more years to think about it. I don't know what I heard, frankly. It is very confusing to me because we have yet to hear what legislation, if any, HHS would support. We know what they are against, but we don't know what they are for.

We also want to applaud the bill's sponsors for ensuring that vaccine compensation decisionmaking in individual cases is left to the Federal court. HHS has an institutional conflict of interest by virtue of its health care cost containment and vaccination promotion responsibilities that would preclude it from deciding fairly whether a claimant qualifies for compensation and, if so, how much.

Their own interpretation of the medical and scientific literature on vaccine reactions demonstrates the Department's bias and its inclination to minimize or even deny the existence of the problem.

We also commend S. 2117 because it guarantees a child's and parent's option to sue under traditional common law principles. It would be the final injustice to require vaccination by law, knowing that some children will be permanently brain-damaged or even die as a result, then to single out these children and their parents to take away their right to common law protection from negligence or unreasonably dangerous products, as the only group of children who don't have the right to go to court. That is hardly real justice. Nor would this be good social policy. The tort law system, even with the limits we pointed out in our testimony in July 1983, and they are substantial, does serve to deter negligence and help augment regulatory incentives for safety. We ought not to simply abolish those incentives. DPT could not support—in fact, would have to oppose—enactment of the bill if it did not guarantee a child's option to sue under the traditional common law tort and contract principles.

We do want to mention two key issues of concern because they come up within our own group. It is important to understand that, while Dissatisfied Parents Together [DPT] supports the bill, we do not claim to represent all the parents in the world or even all the parents who have vaccine-damaged kids. Moreover, there are parents even in our group who have reservations about S. 2117. Their concerns focus around two main points.

Briefly, they fear that the compensation provisions could be used by those who are pushing a very coercive mandatory vaccine system as a basis for saying, "Look, we're going to compensate you if your child gets injured, so you don't have any gripe. Go ahead and get your kid vaccinated. If you don't, then we'll use these coercive methods."

These are not just hypothetical fears; they are based on present real world events. Parents who are refusing to have their children vaccinated are being charged with child abuse or child neglect. Criminal prosecutions are being brought for truancy because the children are being excluded from school. Parents fear that their children may be endangered by these shots, and with some very good, very specific reasons in many cases. Instead of being commended for protecting their children, these parents are being prosecuted.

It is interesting to know that this coercive atmosphere has been created by HHS. The Secretary of HHS has taken occasion to say it is child abuse for parents to refuse to have their child vaccinated. That wasn't said with qualification. It was not said that it is child abuse to do that when your child does not have a contraindication, is not a high-risk child or has not had a prior reaction. The Secretary merely said that it is child abuse to refuse to have your children vaccinated regardless of the vaccine, regardless of the specific circumstances of the child, regardless of the risk. That is the coercive atmosphere that is being created.

Therefore, our people are afraid that the message accompanying enactment of S. 2117 may be, "We'll compensate your child if he is injured, so you can't object."

We are not proposing specific solutions to this problem at this time, but we would be willing to work with the committee on trying to fashion a solution so that this concern can be avoided. We believe that the coercive tone and effect that is conveyed by statements such as those made by the Secretary and resulting from State criminal prosecutions must be eliminated.

The second major parent concern which we think deserves mention is with the compensation part of the bill. The belief has arisen among some that somehow culpable physicians and drug companies will be let off the hook if the bill were enacted, that somehow the taxpayer will wind up paying the cost. I personally do not share the belief that culpable physicians and drug companies are going to be let off the hook, because the bill provides for, even guarantees, the parent's option to sue under common law principles. That means doctors are still liable if they are guilty of negligence and pharmaceutical companies are still liable if they market an unreasonably dangerous product. The bill provides for subrogation and authorizes the Justice Department to bring suit against a negligent doctor or against the manufacturer of an unreasonably dangerous product if the compensation has been awarded. Nevertheless, we share the concern that the bill should not act as a shield for wrongdoing by drug companies or physicians or for the marketing of unreasonably dangerous products. Again, we would be pleased to work with the committee to try to devise any further necessary safeguards in the bill.

There are some other lesser concerns with the bill that we think warrant some attention, and we have included them as an attachment to our testimony.

I would like, with your indulgence, Senator Hawkins, to make a couple closing notes.

The development and deepening of congressional concern about the continuing tragedy of vaccine-induced brain damage is most welcome. With your aid, we hope soon to reach the time when mothers and fathers will never again say, as you saw in the earlier film, "They did this to our children, and then they left us alone with the damage."

But hope is one thing, and reality is another. Every day the status quo continues, we get more unutterably sad phone calls and letters from parents whose children have been maimed or killed. Many of them contain strong documentation. We are not saying that the health problems referred to in each and every letter can conclusively be proved to be vaccine related, but the claims ought to be looked into; they certainly suggest vaccine-induced injury, based on what we know from the available medical literature.

A stop has to be put to this American tragedy as soon as it can be. The answer we propose is not to deny or ignore the dangers of whooping cough; we acknowledge those, but surely denial of these vaccine-injured children and denial of the dangers of the vaccine is not the answer, either.

Yes, we are making slow progress. Two years ago, Dr. Meyer of the FDA testified that within a year or a year and a half we would have that safer vaccine. Well, it is 2 years, and a safer-vaccine is still some years away. We are making some progress, but for some of us progress will not be fast enough.

One year ago when I testified I noted that, even with our daughter's seizure disorder, her motor problems, and her hyperactivity, with her speech impairment, and her learning difficulties, at least we were luckier than the parents of children who had died from the vaccine. Those who knew Julie, who met her, who worked with her, knew that we were very blessed by having a very special child.

But that was 1 year ago, and, as you know, 6 weeks ago Julie died. She died from a cardiac arrest suffered during status epilepticus resulting from her DPT-induced, uncontrolled seizure disorder. Now it is too late for Julie, and it is too late for so many other children; it's 50 years too late, but it is not too late for tomorrow's children.

So we ask you to consider this: at Julie's funeral we read a poem for her that is called "I Carry Your Heart in My Heart." As the committee considers S. 2117, we ask you to do the same—for Julie, for all the injured and dead children like her, for the children who have been injured by the disease as well, but most of all for all of tomorrow's children—please, we ask the committee, "Carry These Children in Your Hearts."

Thank you, Senator Hawkins.

[The prepared statement of Mr. Schwartz follows:]

TESTIMONY BEFORE THE U.S. SENATE
COMMITTEE ON LABOR AND HUMAN RESOURCES
ON S. 2117
("NATIONAL CHILDHOOD VACCINE-INJURY COMPENSATION ACT")

May 3, 1984

Presented by Jeffrey H. Schwartz,
on behalf of Dissatisfied Parents Together (DPT)

Members of the Committee, I thank you for the opportunity to appear before you today. I am here representing the views of Dissatisfied Parents Together (DPT).

In the testimony which follows we plan to cover four main points. First, we want to review the reasons why we believe a bill like S. 2117 is needed. Second, our testimony will recall the ten principles which we previously stated for defining a genuine vaccine victim compensation bill. Third, we intend to assess how S. 2117 measures up to these ten principles. Fourth, we want to identify some key issues and concerns in the bill. Finally, we want to present some brief closing remarks.

I. The Need for a Bill Like S. 2117

At the outset, we want to thank this Committee, particularly Senator Hawkins, Chairman Hatch, and the other co-sponsors of S. 2117, for their leadership in bringing the issue of vaccine safety to national attention. This Committee's hearings on May 7, 1982, and July 22, 1983, have helped demonstrate the need for national legislation such as S. 2117. The record developed in those hearings is an important part of the background of this bill, and any attempt to evaluate the bill must begin with a review of the "findings" which emerge from those hearings.

The hearings (and the underlying medical and scientific literature cited in those hearings) show that - -

> FINDING #1: Pertussis vaccine (the "P" part of the present DPT vaccine) is a relatively crude, impure, reactive vaccine of "unquestioned toxicity", and uncertain character.
>
> FINDING #2: Since Madsen's 1933 Study - - more than 50 years ago - - it has been known that whole cell pertussis vaccines can cause high fevers; convulsion; anaphylactic shock; epilepsy; brain damage; mental retardation; paralysis; loss of hearing, sight, and speech; and even death.
>
> FINDING #3: The vast majority of practicing physicians and public health clinics in the U.S. have until very recently either been uninformed of these facts, unaware of them, or unwilling to admit them. Agreed-upon contraindications to administration of the vaccine have been ignored all too frequently, with resulting tragic consequences. The "contraindications" which have been set out by the quasi-official bodies like ACIP and the AAP have been far too

narrow. This is particularly troublesome as the vaccine system has become more and more compulsory. Physicians have failed to keep adequate records and make adequate reports of severe vaccine reactions. Perhaps most damning of all, physicians have failed to inform their patients and listen to them about vaccine dangers and reactions. Physicians have thus deprived us parents of the information we need to protect our children and deprived themselves of critical knowledge about what is really going on with their patients.

FINDING #4: Physicians have tended to rely on the belief that the government would not license, and pharmaceutical manufacturers would not sell, an unsafe vaccine to children. The doctors have tended to assume that the vaccine had been proven thoroughly safe and effective; adequately tested and screened; manufactured with careful quality control; properly labeled, stored and shipped according to specification; included adequate warnings; and was subject to adequate post-market surveillance. Even more important, universal legal requirements for pertussis vaccination has led most U.S. physicians to conclude that they no longer need to exercise individual judgement in deciding on a case-by-case basis whether, when, and under what circumstances to vaccinate children with DPT vaccine. These legal requirements have led to relaxation of physician vigilance, scrapping of the doctrine of informed consent, and incursion on a parent's first and most fundamental freedom - - the freedom to protect the health and well-being of our children.

FINDING #5: The Health and Human Services Department has performed woefully and inadequately to protect the health of our children in this area. It has failed for over 40 years to push for a vaccine safer than the whole cell pertussis vaccine. It has not provided an adequate regulatory framework to assure that whole cell vaccines are made and administered as safely as possible. It has for years "studied" the need for compensating children who are severely injured by vaccines, yet has not put forth a single proposal. It has strongly encouraged state-laws mandating vaccination as a pre-condition for school entry, yet has failed to acknowledge the need for flexibility and sensitivity in the system. The Department has kept vaccine policy making in the hands of the few and out of sight of the many. It has not insisted on adequate accountability by doctors and vaccine makers and it has not been willing to be accountable itself. Perhaps worst of all, the Department has by and large refused to get the facts, know the facts, and share the facts with the public.

FINDING #6: In the face of these realizations of the last two years parents have had to turn to the courts, to the Congress, and ultimately to ourselves to redress these grievances. That is why Dissatisfied Parents Together (DPT) came into being. That is why we developed our own parent information packet on pertussis vaccine. That is why increasing numbers of lawsuits are being filed on behalf of vaccine-damaged children. That is why a bill like S. 2117 is needed.

FINDING #7: There is a "Middle Ground" for better protecting our children's health. We need not be blind to the dangers of the vaccine in order to be concerned about the dangers of the disease. We need not ignore concerns about whooping cough in order to avoid vaccine-related brain damage. Being concerned about both the disease and the vaccine, we can work in an informed and balanced way to safeguard our children's health.

II. DPT's Ten Principles

In our July 1983 testimony before this Committee, Dissatisfied Parents Together set forth ten principles for achieving this "Middle Ground". We called these principles for distinguishing genuine "vaccine victim compensation" legislation from proposals which, in practical effect, would be "vaccine victim condemnation" bills. These ten principles are re-stated below:

1. The bill should expressly acknowledge that pertussis vaccines can, and in some instances do, cause serous reactions, including seizures, brain damage, even death.
2. The bill must not simply be an effort to sweep the DPT-vaccine problem under the rug. Compensating those who are injured by the vaccine and continuing to require virtually all children to take this admittedly "dirty" vaccine is not an acceptable solution. The bill should contain positive commitments and incentives to reduce the risks of reactions to the current vaccine and to promote development of safer vaccines. As a minimum these commitments and incentives should include: requirements for adequate written information to parents on the risks of the vaccine and on the contraindications to the vaccine; adequate recordkeeping and reporting by doctors and clinics giving the vaccine; more stringent quality control and testing requirements by manufacturers; and more leniency in defining categories of high risk children who should not be required to receive the vaccine.
3. The bill must not restrict in any way a parent's (or child's) right to sue under existing law. The choice as to whether to sue under existing law or to seek this new form of compensation should belong entirely to the parents.
4. The bill must provide an opportunity for effective compensation for all seriously vaccine-injured individuals, regardless of how long ago the injury may have occurred.

5. The bill should provide a relatively simple, speedy, inexpensive, non-adversarial mechanism for compensation of vaccine-damaged children.

6. The bill should contain safeguards to assure that the award of compensation will not depend on proof by the claimant of who the vaccine manufacturer was; on proof of negligence by the doctor or defect in the vaccine; or disproof of all possible alternative explanations for the child's injuries.

7. The bill should guarantee a level of compensation which is adequate to enable the damaged child to realize his or her maximum potential and enjoyment of life. Allowable compensation must not be limited by any arbitrary fixed dollar ceiling or by the current availability of services (or lack thereof) to meet the vaccine-injured children's needs.

8. The bill must define allowable compensation as being available for the life of the injured person in the case of permanent injuries, and as covering all necessary medical, rehabilitation, special education, therapy, behavioral and emotional counseling, custodial care, residential placement and other necessary expenses. At a minimum compensation should also be provided for the victim's loss of earned income and pain and suffering; and in the case of a child's death being caused by the vaccine, a substantial death benefit payment should be provided for the parents.

9. The persons and institutions deciding vaccine-damage compensation claims under the new optional approach must be completely independent of any governmental or private agency responsible for promoting vaccines or for controlling health care costs.

10. The financing mechanism of the bill should assure that the payment of compensation awards will not be deferred or reduced because of budget deficits or government program "cut-backs." While the Treasury should be the ultimate back-stop to assure timely and complete payment of compensation, those who have benefitted from the vaccination requirements should have primary responsibility to finance the system. The financing system should be designed to recover costs from responsible parties in any cases of vaccine-injury due to negligence in the manufacture or administration of the vaccine or to defect in the vaccine itself.

III. Assessment of S. 2117: How It Measures Up to the Ten Principles

We are pleased to say that we believe S. 2117 meets all ten of these principles, and thus Dissatisfied Parents Together would support enactment of S. 2117. We do not say this without reservation or concerns, however. And these concerns need to be clearly noted. But before we do, several key points need to be made about the strengths of this bill.

We are particularly pleased by Parts C and D of the bill. Together, these provisions will create statutory mandates for development and use of safer vaccines and for strengthening of the current system to prevent serious vaccine reactions. These mandates will create non-discretionary duties. If the Secretary of HHS fails to use the authority she has under any law to achieve these goals, a citizen suit may be filed and the courts could mandamus the Secretary to act.

Likewise, these parts of the bill mandate certain safeguards to be carried out by doctors and other health care providers. These new duties would become part of a physician's "standards of practice or care." Any failure to carrry out their mandated responsibilities would at least create a presumption of negligence. A pattern of refusal or failure to implement the law could lead to punitive damages under tort law law or be considered in licensure review proceedings. We are please to note that the State Legislature of Maryland has recently passed legislation which is very similar to Part C of S. 2117.

We also want to point out the importance of the procedural and judicial reveiw provisions of S. 2117. The vaccine licensure process and vaccine policy process have not in the past been open to the public. Parent input has not only not been solicited; when offered, it has frequently been totally ignored. The presently closed system needs to be open and accountable, and these provisions for procedural openness and judicial review will help produce healthier children and a better system.

Without Parts C and D of S. 2117, Dissatisfied Parents Together would be unable to support the bill. Compensation without "prevention" and safeguards would simply sweep the problem under the rug. We think in fact that the single greatest strength of the bill is its open acknowledgment that there is a problem and it needs to be dealt with.

We also want to applaud the bill's sponsors for insuring that vaccine compensation decision-making in individual cases is left to the federal court. HHS has institutional conflicts of interest by reason of its cost containment and vaccine promotion responsibilities that would preclude it from deciding fairly whether a claimant qualifies for compensation and if so, for how much.

We also commend S. 2117, because it guarantees a child's option to sue under traditional common law principles. It would be the final injustice to require vaccination by law knowing that some children will be permanently brain damaged as a result, then to single out these children to take away their right to common law protection from negligence or unreasonably dangerous products. Nor would this be good social policy. The tort/contract system, even with the limits we pointed out in our testimony in July 1983, does serve to deter negligence and help augment regulatory incentives for safety. Dissatisfied Parents Together (DPT) could not support, in fact would have to oppose, enactment of any bill which did not guarantee a child's option to sue under the traditional common law priniples of tort and contract.

IV. Key Issues and Concerns

The Committee should know, of course, that Dissatisfied Parents Together (DPT) does not claim to represent all parents concerned about pertussis and pertussis vaccine. Nor are all the parents in our group united in their support for S. 2117. There appear to be two main concerns about the bill that warrant particular attention.

First, some parents feel that the "compensation" provisions of the bill will be used by HHS and state health agencies to continue (and even strengthen) certain deplorable coercive practices. They hear Secretary Heckler say, without qualification, that it is "child abuse" to fail to vaccinate children. They see state school and health officials suing parents for "child neglect," "child abuse," and "truancy," when the parents, in fear for their children's health, refuse to have their susceptible children inoculated. They see state attorneys general suing to take guardianship of children to forcibly vaccinate them when parents refuse. These parents fear that the "compensation" part of S. 2117 will be used as a justification for the indiscriminate use of the current pertussis vaccine, even in the face of principled objection by parents. They fear health officials will brush aside their concerns by saying, "We'll compensate your child if he's injured -- so you can't object."

We are not proposing specific solutions or amendments to meet this set of concerns at this time. But we think these concerns deserve to be addressed, and we would be pleased to work with the Committee and those parents who have most strongly voiced these concerns to assure that the compensation provisions will not be used as a green light for governemnt coercion.

The second major parent concern with the compensation part of the bill is the belief that it may somehow let "culpable physicians and drug companies off the hook" and put the taxpayer "on the hook instead." We do not share this belief. That is because the bill preserves, even guarantees, the parent's option to sue under common law and it provides for subrogation and authorizes Justice Department suits against drug companies or physicians in appropriates cases. Nevertheless, we share the concern that this bill not act as a shield for drug company and physician wrongdoing or unreasonably dangerous products. Again, we would be pleased to work with interested parties and the Committee to provide necessary and appropriate safeguards in the bill.

Other parent concerns appear to us to warrant some further discussion. See, for example, attachment #1 (Letter from Daniel E. Resciniti to Jeff Schwartz, 12/12/83, re S. 2117). Bearing these concerns in mind, Dissatisfied Parents Together favors prompt action to pass S. 2117, the "National Childhood Vaccine-Injury Compensation Act."

V. A Closing Note

The development and deepening of congressional concern about the continuing tragedy of vaccine-induced damage is most welcome. With your aid, we hope soon to reach the time when mothers and fathers will never again say: "They did this to our child, then they left us alone to deal with the damage."

But hope is one thing, and reality is another. Every day the status quo continues, we get more unutterably sad phone calls and letters from parents whose children have been maimed or killed. A stop must be put to this American tragedy as soon as we can. The answer we propose is not to deny or ignore the dangers of whooping cough. But surely denial of these children is not the answer either.

Yes, we are making slow progress. But for some of us progress will not be fast enough. One year ago when I testified, I noted that even with our daughter's seizure disorder, motor problems, hyperactivity and speech impairment, at least we were luckier than the parents whose children had died from the vaccine.

That was one year ago. Six weeks ago, Julie died from a cardiac arrest, suffered during status epilepticus resulting from her DPT-induced uncontrolled seizure disorder. Now it is too late for Julie. And it is too late for so many other children — fifty years too late. But it is not too late for tomorrow's children.

At Julie's funeral, we read a poem for her: "I Carry Your Heart in My Heart." As you consider S. 2117, we ask you to do the same -- please, for Julie, for all the injured and dead children like her, and most of all for tomorrow's children, please "Carry These Children in Your Hearts."

Attachment #1

DANIEL E. RESCINITI
3 Goethe Street, Binghamton, New York 13905
607-729-3934

December 12, 1983

Jeff Schwartz
c/o DPT Box 563
1377 K Street NW
Washington, DC 20005

Dear Jeff:

RE: S-2117

I want to thank you for the courtesy you extended to me in our phone conversation on December 3, 1983, and again express my gratitude to the DPT group for the efforts put forth in negotiating the needs of vaccine-injured children. Senators Paula Hawkins and Orrin Hatch, having introduced S-2117, confirm that side-effects do occur following routine vaccine immunization and that victim compensation is necessary.

Having gone through the past twenty years with two of my sons injured by DPT, the hardships, both emotional and financial, cause me to ask questions and offer a few suggestions:

1. A form and pre-addressed envelope to the CDC should be given to parents to report any adverse reaction following immunizations. The CDC should acknowledge receipt of such a notice within ten (10) days to the parent(s). The CDC should monitor and report, at ten (10) day intervals, all reported vaccine reactions to the Secretary of Health and Human Services. Accordingly, this should not be a burden if, in fact, the statistics, as published to date, are correct.

2. The insurability for unrelated health care should be guaranteed for life. This should be broad coverage and should include all dental as well as all medications for conditions from acne to ingrown toe nails. My experience with Medicare, Medicaid, and insurance companies -- "This is covered, this is not," is an unnecessary hardship.

3. In my particular case, medication has not and does not control the convulsive seizures or spacicity my sons experience. I find this unacceptable and therefore I look to the medical pioneers. Presently, and for the past two and one-half years, a prominent research neurosurgeon is precluded from implanting cerebellum stimulators as a means of controlling seizures by the FDA. The stimulator is permitted under investigation (experimentally) for cerebal palsy patients. Of these CP patients, many also have seizures. Implantation of the stimulator has proven successful in reducing the spacicity and seizures have diminished or have entirely abated. It seems that

the FDA's interest in the public at large eclipses the need of orphan drugs and medical devises due to the rigid protocol it has established. The FDA will allow the use of the obsolete devise that is worn externally (Grandfather Rule), however, the newer implantable devise remains under review. Essentially, my suggestion is that a research doctor be permitted to use, by prescription, medical devises to improve the quality of life in his/her patient once accepted by the patient or the patient's guardian and that the FDA waive its strict protocol under specified circumstances.

4. A child who becomes damaged and who is eligible under the bill may live forty years, plus or minus. Does the death benefit of $300,000-700,000 remain or is indexing incorporated due to inflation or deflation?

5. Hypothetically, the 10-year option is selected, $250,000 is placed in the initial trust. The child dies one year later. Expenses were $25,000. What happens to the $225,000 remaining in the trust? Is the death benefit separate from this balance?

6. I have begun legal action concerning DPT-related injury. I now elect to come under the Compensation Act. Who would pay the already incurred legal expenses?

7. The provision to appeal is unclear to me and does not address a time limit for a decision once an appeal is made.

8. If an appeal is made through an attorney, who pays the attorney, win or lose?

9. False claims and possible corruption are always a possibility. Will the Justice Department police this bill and apply mechanisms to ensure the primary intent of the bill?

10. Is the panel or Federal Magistrate subject to income disclosure?

11. Allowances for development of safer vaccines is mentioned. Can "for possible genetic research" be included?

12. If the 10-year option is selected, say $250,000, and the trust is exhausted after eight years due to unforeseen expenses with the next two years becoming even more expensive, who subsidizes these unforeseen and unexpected costs?

13. Parent transportation and lodging to various medical centers for treatment should be separate from trust options and be paid as needed.

14. The costs to administer this Compensation bill should be budgeted and monitored by Congress.

Jeff, my intentions are not to discredit the bill as submitted, however, my suggestions, questions, and concerns are being made available to you for comparison with concerns of other parents to adequately meet the needs of injured vaccine victims. Should you desire clarification of any of my comments, please do not hesitate to contact me.

Sincerely,

Daniel E. Resciniti

Daniel E. Resciniti

Senator HAWKINS. Thank you, Jeff. You are to be commended for being such a leader in this whole movement, and possibly because of your keen interest and leadership we will be able to solve this problem for other children, and little Julie would not have died in vain.

Mrs. Gary, grandmother of a child who had problems with this vaccine, would you like to tell us about it?

STATEMENT OF DONNA GARY, WAYLAND, MA

Mrs. GARY. Thank you, and good morning, Senator Hawkins.

My name is Donna Gary. I am a constituent of Senator Kennedy's from Massachusetts.

Our family should have celebrated our very first granddaughter's first birthday last month. Instead, we will commemorate the anniversary of her death the end of this month.

Our granddaughter, Lee Ann, was just 8 weeks old when her mother took her to the doctor for her routine checkup. That included, of course, her first DPT inoculation and oral polio vaccine.

In all her entire 8 weeks of life this lovable, extremely alert baby had never produced such a blood-curdling scream as she did at the moment the shot was given. Neither had her mother ever before seen her back arch as it did while she screamed. She was inconsolable. It was even difficult for her mother to drive them home for daddy's consolations while she went to the pharmacy. She needed to purchase the infant Tylenol the doctor suggested for the baby if she developed a possible slight fever. Even her daddy could not understand Lee Ann's uncharacteristic screaming and crying.

Four hours later Lee Ann was dead. "Crib death," the doctor said. "SIDS." "Could it be connected to the shot?" her parents implored. "No." "She just had her first DPT shot this afternoon. Could there possibly be any connection to it?" "No, no connection at all," the emergency room doctor said definitely.

My husband and I hurried to the hospital the following morning after Lee Ann's death to talk with the pathologist before the autopsy. We wanted to make sure he was alerted to her DPT inoculation such a short time before her death—just in case, just in case there was something else he could look for to make the connection. He was unavailable to talk with us. We waited, waited 2½ hours. We never even had any confirmation that the pathologist even knew we were there. Finally, we got to talk to another doctor after the autopsy had been completed. He said, "It was SIDS."

In the months before Lee Ann was born I regularly checked with a friend as to the state of her grandchild's condition. He is nearly a year and a half older than Lee Ann. On his first DPT shot he passed out cold for 15 minutes, right in the pediatrician's office. "Normal reaction for some children," the pediatrician reassured.

The parents were scared, but they knew what a fine doctor they had. They trusted his judgment.

When it was time for the second shot they asked, "Are you sure it's all right? Is it really necessary? Was the last time that Jonathan was unconscious for 15 minutes really nothing to worry about? He's only 4 months old."

Their pediatrician again reassured them. He told them how awful it was to experience, as he had, one of his infant patient's bout with whooping cough. That baby had died from whooping cough.

Jonathan had his second DPT shot that day. Jonathan became brain-damaged.

The parents learned from their own research later that the doctor should have checked the family's neurological history. Jonathan's mother has a form of epilepsy. A history in the family of this should be a contraindication for a baby to receive pertussis vaccine. A brain damaged child—no connection to the shot, Doctor?

Death is hard for the survivors to live with. Death of a child is even harder to live with. But death is final and we do somehow manage to go on living.

There is also a living death. Having to be or to be the one to care for a brain-damaged child, teenager, adult day after day, month after month, year after year, has to be the absolutely most physically straining, emotionally as well as financially draining situation that any human or humans can bear.

I understand this hearing is to address the compensation needed to ease at least the financial burden of those who are afflicted with vaccine-related problems. I am in full agreement with the Dissatisfied Parents Together presentation of that part of the issue and will use this time to emphasize those points that are as equally important in this bill.

So many questions came to mind through the loss of our precious grandchild. It was not until almost 6 months of searching, reading, inquiring, that I touched based with the Dissatisfied Parents Together group in Washington, DC. How happy I was to find an intelligent group of people who had been asking the same questions as I. They had formulated a statement of purposes and policies that put into actual words some of my own vague ideas. They also informed me of Senate bill 2117. I even plowed through reading the entire bill they sent me, but I was grateful for the summary they provided that made it possible for me to comprehend. I wrote my Senators and encouraged my family and friends to write their Senators as well to pass such an important bill.

Being a political novice, I was puzzled a few weeks ago to learn S. 2117 was referred to the Labor and Human Resources Committee. Whatever does that mean? So here I am, hoping to learn the meaning.

This past week I had opportunity to read through the May 7, 1982, and July 22, 1983, printed copies of the hearings of this committee. I am dismayed to learn that this same talk has been going on for 2 years. In fact, I understand it is 3 years before this. I am dismayed that 2, 3 years have gone by and nothing has seemed to progress to incorporate what seems so obvious and so necessary to keep from destroying any more babies, and to compensate financially those who have already been damaged for life.

I read in Dr. William Foege's, the former Director of CDC, testimony in the 1982 hearing on page 6 where he refers to the only U.S. study on vaccine reactogenicity that was done at UCLA between 1978 and 1979. He refers to the 15,000 doses—not number of children, doses—in which 9 children had convulsions and 9 had episodes of collapse. He does not mention the two infants who died within 4 days of the DPT inoculation.

It was concluded in the report that since they had previously set a 48-hour limit on any possible death being related to the vaccine, and since—please hear this—"statistically," dealing with the number of children they were, they would expect two SIDS deaths, therefore, these babies were diagnosed as SIDS in spite of what the infants were experiencing clinically before they died. No connection, really? No connection?

No wonder doctors can believe no connection, if this is the type of conclusion drawn in a scientific study.

If my comprehension level is accurate in what I read, I believe the Japanese people refused the pertussis vaccine their Government provided because of only two deaths in 1975. How were they able to research so quickly a safer and, apparently, effective vaccine that they are now using? Where is our research at this point? When will we have a safer pertussis vaccine?

At this same 1982 hearing Dr. Vincent Fulginiti of the American Academy of Pediatrics criticizes the television program, "DPT, Vaccine Roulette," aired here in the Washington area. He says, on page 111, "We at the American Academy of Pediatrics believe it imperative that such sensationalism not go unchallenged."

He then goes on to enumerate statistics including, "Pertussis can cause brain damage in as many as one child in 8,000."

How accurate are our statistics on adverse reactions to vaccine, Dr. Fulginiti, when parents have been told, are still being told, "No connection to the shot, no connection at all."

What about the mother I have recently talked with who has a 4-year-old brain-damaged son? On all three of his DPT shots he had a convulsion in the presence of the pediatrician. "No connection," the pediatrician assured.

This mother believed the doctor, wondered what had caused her son to lose all motor control. She lived with this situation for a year and a half. Then she saw the Phil Donahue television program on vaccine reactions which I assume was a result of the local show in Washington that Dr. Fulginiti called sensationalism. This mother needed help. The doctor had told her, "No connection to the shot." She finally called an acquaintance who is a lawyer.

Who else is in a similar condition and has not had the opportunity to see the sensationalism of a TV program and still believes there is no connection to their own child's problem from a vaccine?

Another acquaintance heard on a television program that it is important to record the manufacturer's name and lot number of the vaccines being administered to children; for one of the reasons, in case it might be necessary to recall a lot considered a "hot lot." Why did she have to tolerate almost a sneer as well as a sarcastic remark from her doctor while he reluctantly followed her request? Apparently, it does take a Federal law for some doctors to do the obvious.

It is hard to imagine that doctors do not automatically record adverse reactions to vaccines on the patients' charts, but, again, it needs to be spelled out in law to make it happen. These reactions must also be reported to a central agency in order to accumulate more accurate figures. I find it hard to believe that in this computer age a system of accurate statistics cannot be effected in a simplified manner.

I talked with a father in a town adjoining ours whose son died at the age of 9 weeks, several months before our own granddaughter's death. It was the day after his DPT inoculation. "SIDS" is the statement on the death certificate.

Their pediatrician is a teaching professor at Harvard Medical School. These parents had another baby this past winter. It was on their own insistence that the baby be given only the DT and not the "P" in her routine inoculations. The doctor saw absolutely no connection between their other child's shot and death. The parents are not that positive. The doctor teaches our coming generation of doctors.

Are the statistics that the medical world loves to quote to say, "There is no connection," really accurate, or are they based on poor diagnoses, poor recordkeeping?

If it is true that adverse reactions to pertussis vaccine are so very rare, how can one ordinary person like me know about:

No. 1, a personal friend whose grandchild is brain-damaged due to pertussis.

No. 2, our own daughter's child, dead within 4 hours of her first DPT shot. I have learned within the past few months that the significant type of scream, arching of the back, and unnatural limpness Lee Ann experienced are called encephalopathic manifestations.

No. 3, an acquaintance in an adjoining town whose baby died within 24 hours of DPT inoculation.

No. 4, the 4-year-old brain-damaged child in Canton, MA, who convulsed on all three DPT shots in the doctor's presence.

No. 5, I have not previously mentioned Debbie and Steve, who are at this hearing now. I talked with Debbie a week ago. Their baby received his first DPT shot the evening of this past March 7. He was dead in the morning. "No connection. SIDS."

No. 6, a young mother from Medfield, MA, who is interested in starting a Massachusetts Chapter of Dissatisfied Parents Together with me. She feels she is lucky. Her 2½-year-old daughter experienced daily seizures for only 1½ years, semicontrolled by drugs, but it was a hellish long time to live through. At least her neurologist did not say, "No connection." He is sure it was a reaction to pertussis vaccine.

Six cases. How many lives involved? Certainly not only the victims themselves—whole families, coping, grieving.

What is being done to provide a safer vaccine? Who is overseeing? Will it be the same scientists and doctors who have been overseeing in the past? How much longer does the public have to wait? How are physicians, clinics going to be held accountable to see that parents are informed of the possible reactions? Who and how are those children who should not receive the vaccine to be identified before they are damaged—or dead?

How can doctors be reeducated as to what a dangerous vaccine it is they are so casually administering? Why is the vacine we use 1.6 times the strength that the World Health Organization recommends? Why don't various countries get together to compare vaccines? Why are those organizations that can provide answers not busily trying to "find the connection," instead of refuting the evidence of case studies which involve the people affected? The medical associations seem so quick to squelch even their own doctors when these doctors try to point out their own research and discoveries of the problems that exist.

I admire those doctors who question what has been and still is happening. I would like to include with my testimony a report from the Physicians for Study of Pertussis Vaccines, a group of physicians in California who are much concerned with this problem of pertussis vaccine. The report is written by Kevin C. Geraghty, M.D., and is entitled, "Death Events Following DPT in Northern California."

Today is the National Day of Prayer. My prayer is that this committee be instrumental in doing what needs to be done—and soon. May there not be yet another year pass by with more children afflicted and some dead because those who can do so refuse to "make the right connection."

Thank you for the privilege of speaking to this group.

[Information supplied for record follows:]

Physicians For Study of Pertussis Vaccines
Box 345
11072 San Pablo Ave.
El Cerrito, California 94530

March 17, 1984

DEATHS FOLLOWING DPT IN CONTRA COSTA COUNTY
(CALIFORNIA) INFANTS: FIRST HALF OF 1983

POSITION: PSPV feels that this article submitted for publication shows that certain infants are and have been dying of DPT perhaps since the 1940's. We feel due to the past effectiveness of the present pertussis vaccine, a new benefit-risk scenario has evolved, whereby a "mid-course correction" is long overdue. The current observation of atypical SIDS deaths suspiciously following DPT requires immediate investigation using active surveillance techniques. Children dying shortly (within 4 days) of DPT should have appropriate clinical histories obtained emphasizing family and early personal signs of allergy or prior history of apnea. Objective data consisting of full HLA typing, plasma insulin levels, total IgE and levels of antibodies against bovine serum albumin and other milk proteins should be obtained in the proper fashion. This suggestion is based on research in mice from Stanford University (Steinman, et al) and our clinical histories in over 30 human cases of shock-like deaths ("SIDS") and classical encephalopathic cases. Samples for serum studies must be obtained so as not to "contaminate" samples with blood from the inferior vena cava. Objective data must be correlated with an appropriate staging based on the clinical mode of death. Our interest is in that subset of infants dying with a clinical history of symptoms and signs long associated with hypotonic--hyporesponsive episodes (HHE) in classical DPT non-fatal reactions. The practice of coroners classifying such deaths as "SIDS" must be decried as being technically incorrect. The suggestion for "Toxic (or shock-like) deaths temporally following DPT" is made.

KCG/cg

Title: DEATH EVENTS SHORTLY FOLLOWING DPT IN NORTHERN CALIFORNIA

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Reprints: None

Grant Support: Author's private practice only

ARTICLE SUBMISSION

TITLE: Death Events Shortly Following DPT in Northern California

AUTHOR: Kevin C. Geraghty, M.D.

Death Events Associated with Natural Pertussis and its Vaccine:

Madsen (1) in 1933 and Werne (2) in 1946 reported shock-like deaths following within 24 hours of receipt of pertussis vaccines. In the past, epidemics of whooping cough have been associated with sudden death events (3) in infected infants. More recently, the Swansea Research Unit (4) reported in 1981 that two of the three natural pertussis deaths involved infants found "dead in bed". These infants were ages 4 and 5 months.

Bernier (5) reported in 1982 on five deaths occuring within 24 hours of DPT administration during a 1978 vaccination drive in Tennessee. All five infants received DPT prepared by the same manufacturer and four from the same lot. All were listed on death certificates as SIDS events. Clinical histories of events in this study following DPT and prior to death were not reported. This study was originally included in the 1979 report to the Surgeon General (6). The newly instituted Monitoring System for Illness Following Immunizations (MSIFI) (7), a passive surveillance system, was credited with recognition of this potential "hot lot" situation that had led to this followup investigation. More recently, Torch (8) and Baraff (9) reviewed SIDS death certificates and then obtained corresponding vaccination histories. All three studies (5,8,9) while not citing clinical histories following DPT administration, showed clearly a sensitivity to the first several days following administration of DPT. They also showed sensitivity to the first DPT injection. Fulginiti (10) has editorialized cautiously on the biological credibility of a potential cause and effect relationship. This would be based on well-known, non-fatal shock and sudden collapse events following DPT administration. Additionally, during the recent definitive American study on DPT reactogenicity by Cody, et al (11), two SIDS events (12) occurred in the prospective phase shortly after the observation period of 48 hours following DPT used in this study. For the past several years, the product insert accompanying DPT vaccines from major manufacturers has noted this troublesome temporal relationship.

The Contra Costa Study:

The author monitored all unexplained death events of infants under one year of age in Contra Costa County, northern California during the first half of 1983. There were ten such episodes. In all ten cases the cause of death was stated as SIDS on death certificates. All the families were interviewed and the personal and family history of all the deceased infants was obtained including history of illnesses and vaccinations. Autopsy reports and death certificates on all cases were obtained. The appropriate state agency was notified to ascertain manufacturer and lot numbers for vaccines. Typically this potentially important information is not being recorded by physicians and clinics in the private sector. Three of the cases (#4,5,6) were clinically classical for SIDS and had no antecedent illness or recent DPT injection history. Four cases (#7,8,9,10) showed clinically classical SIDS histories with a non-suggestive DPT history. In these 4 deaths, however, the infants had apparently recovered from an antecedent viral respiratory illness associated with fever approximately 7-14 days earlier. In the remaining three cases there were disturbing clinical histories not typical of SIDS or of the other 2 groups which commence shortly after DPT vaccination. The clinical histories following DPT in all three infants as noted in Table #1 are quite analogous to the clinical histories of hypotonic-hyporesponsive episodes (HHE) as reported in Table 4 of the article on DPT reactogenicity by Cody, et al (11). The development of HHE following DPT occurs in 1:1750 injections (11) and is a contraindication to further DPT receipt. DT vaccination is continued in the sequence. All three deaths in this group were classified as SIDS by the coroner's office as were all those in the other 2 groups. There was no association with manufacturer or lot number in any of the cases or groups reported here.

Temporal Relationships:

Fulginiti (10) has reviewed the inherent dangers in imputing causality to temporally related events. The NIH sponsored Cooperative Epidemiological Study of Sudden Infant Death Syndrome Risk Factors has been used to examine this temporal association between DPT and SIDS events. Hoffman (13) concluded in his preliminary report on the first half of the study, "In summary, the data from the NICHD Cooperative Epidemiological Study of SIDS Risk Factors strongly supports the view that DPT immunization is not a factor in the etiology of SIDS". Both Fulginiti (10) and Hoffman (13) make the fundamental error of not incorporating clinical staging into their respective study models for assessing temporal relationships. Fulginiti's theoretical model would be flawed by this ommission and Hoffman's was. In the latter case, the major criterion for inclusion of cases for study was designation by a medical examiner or coroner based on a standardized necropsy protocol. Based on our experience in this report, three clearly classical clinical histories for DPT mediated adverse reactions were admixed with seven classical clinical SIDS events. The author feels a need for staging SIDS events by both clinical features as well as their temporal relatedness to DPT. Studies addressing SIDS as if it were a homogenous condition may thus be technically unsatisfactory. Further suspicion is raised by the lack of randomness in reported data. This study similar to those cited earlier (5,8,9) showed a definite trend towards these temporal death events occurring predominantly on the occassion of the first DPT injection. Given the well-confirmed precedence for classical SIDS events mainly between two and six months of age (13), one should expect to see deaths temporally associated with DPT vaccination to be more equally distributed and without a distinct bias to series number. The apparent sensitivity to the first days following DPT could reflect observer bias in a passive surveillance system such as MSIFI, however such a pattern prevails also in studies (5,8,9) where all SIDS events are retrieved and reported in terms of receipt of DPT in a retrospective active surveillance fashion.

Causal Relationship:

If one were to attempt to impute causality to these DPT temporally associated death events reported here and elsewhere, then, in addition to the strongly suggestive clinical and temporal histories, one would have to submit reasonable evidence for the existence in whole cell pertussis of putative elements capable of precipitating such events. Given the occurrence of similar death events in the natural disease (3,4) and following shortly after its vaccine,(1,2,5,8,9,12) then such an exercise is clearly warranted. The long noted occurrence of apnea and cyanosis in the natural disease state (14) is an additional cause for concern.

Immunological and Other Biological Properties Associated With Pertussis Vaccines:

The chief biologically active substances associated with whole cell vaccines (15) are dermonecrotic toxin, agglutinogens, hemagglutinin, endotoxin and pertussigen. Pertussigen is an apparent molecular mosaic with multiple activities. Chief among these activities are Histamine Sensitizing Factor (HSF) (15,16) and Islet Activating Protein (IAP) (11, 16, 17, 18).

HSF appears to be the chief facilitator of , and an essential element in, the induction of Experimental Allergic Encephalopathy (EAE) (16,19) in animals. Additionally, HSF renders mice or rats unusually sensitive to the lethal effects of histamine (15,20). These physiological changes are similar to certain clinical findings in human atopy (21,22). Induction of sensitization is variable in onset and somewhat dose dependent (21). Once induced the activity is active for several days (20,21). An ancillary attribute of HSF or pertussigen is to act as an adjuvant to production of reaginic (IgE) antibodies (21). Recently, Steinman (23) has reported on a murine model for pertussis encephalopathy. An inbred strain of mice showing linkage to the H-2 locus for this reaction is used. In this model, selected susceptible strains, showed a 90% fatality rate by 6 days following vaccination with pertussis vaccine. In non-susceptible strains the fatality rate was zero. Autopsy of these encephalopathic mice, following what the author's described as a "lethal shock-like syndrome", showed "diffuse vascular congestion and parenchymal hemorrhage in both the cortex and white matter". Precipitation of these death events required presensitization to bovine serum albumin. Thus in this atopic mouse model, death follows prior sensitization to probable HSF once apparent IgE antibodies combine with externally supplied antigen releasing endogenous histamine. The authors point out that most human infants possess titers of antibodies against bovine serum albumin. This is due to ingestion of milk, milk-based formula or breast milk containing milk antigens from maternal ingestion. In our series of three non-SIDS deaths shortly after DPT, two of the infants had personal histories and all had family histories strongly suggestive of atopy. The same pattern is true of the overwhelming majority of the other ten unreported "SIDS" events cases that we have reviewed showing these abrupt, atypical SIDS histories in temporal relationship to DPT. In our group of twelve surviving encephalopathic children all have clinical histories of atopy and asthma. To date, only part of this group has been objectively tested by IgE assay, selected RAST testing and HLA determinations. All tested have shown the presence of objective atopy.

In rats immunized with pertussis vaccine there occurs a markedly enhanced hyperinsulinemia in response to insulin secratogogues such as glucose, sulfonylureas, and B-adrenergic agents (18,24). This action has been shown to be a property of IAP. The onset of this action in rats is rapid and long-lasting (24). It has been suggested that this induced hyperinsulinemia may lead to hypoglycemia which then exaggerates the toxic action of histamine (24).

In 1978 Hannik (25) demonstrated that normal human infants given standard pertussis vaccines showed slight but significant elevations in their plasma insulin levels. These changes were dose-related relative to the opacity units of the particular pertussis vaccine given. Their was a minimal effect on the plasma glucose levels in this small group of children. The author suggested that, "Infants who show serious reactions following pertussis vaccination suffer from a failure to maintain glucose homeostasis". Appropriately, the author further suggested that this possible human clinical expression be looked for in larger groups and in those countries with higher opacity unit pertussis vaccines. Cameron (26,27) has noted the distinctly higher opacity units of the American pertussis vaccine and expressed concern in the latitude for assay limits set by the FDA for "protective units". The American vaccine is stated to significantly differ in both of these characteristics from WHO standards.

In the nonprospective phase of their 1978 study, Cody, et al (11,12) reported on 2 cases of "Reye's syndrome like" reactions. This 4-month old infant (NR-1) presented in profound shock at the beginning of the third day following his second DPT. The blood sugar was not detectable, there was a lymphocytosis of 34,000 with 95% lymphocytes. A plasma insulin was drawn but results are not reported. Following profound chronic hypotension requiring Dopamine, the child expired 20 hours after presentation. Bacterial and viral cultures were negative. Autopsy findings showed bilateral adrenal hemorrhage, cerebral edema, necrosis and fatty infiltration of the liver.

The second "Reye's syndrome-like" case (NR-2) reported by the group, was a 2-month old infant who had received his second (sic) DPT four hours prior to presentation at an emergency room with a fever of 105. Following cooling measures the child was discharged home. Twenty hours after vaccination, the child presented again to an emergency room with generalized afebrile seizures. The blood sugar was 13 mgs%. Seizures were controlled with IV valium and glucose. Septic workup was negative. The child was reported in this study as neurological normal based on seven day followup. The author, following reading of these two interesting reactions has identified two similar clinical cases. The first presented with seizures 24 hours after DPT with associated documented hypoglycemia and hyperinsulinemia. This child is alive, has chronic poorly controlled seizures, spasticity and requires custodial hospital care. The second child was a shocklike death 24 hours after DPT quite similar to NR-1. This case was diagnosed clinically at the time as Waterhouse-Friderichsen syndrome despite a negative workup. A report on these cases is in preparation, In this matter it should be noted that cases of "Reye's Syndrome" temporally associated with DPT were noted in the British National Childhood Encephalopathy Study (28). Similar cases are listed in the MSIFI reports of recent years.

SUMMARY:

In summary, the author has sought to explore the possibilities that certain rare sudden death events shortly after DPT administration may not only mimic similar reports in the natural disease but that may have more than a mere temporal relationship. By clinical history they correspond to analagous reactions seen in the natural disease state. They have well-known milder analogues in nonfatal HHE reactions. The basic research into pertussigen and its properties would seem to have sometime ago established a pathophysiological basis for such reactions. Cases and reports demonstrating clinical similarities in human infants to well-established animal results have been reviewed. The author strongly urges increased awareness of the feasibility of a causal basis for these rare reactions.

Clinicians should respond promptly to infants and children reporting HHE-like events following DPT. Monitoring of glucose, insulin and other acute phase reactants has therapeutic, diagnostic and epidemiological advantages. Long term neurological followup of such cases may be prudent. Clinically staged cases should have HLA typing and certain atopic parameters assessed. In extreme presentations the use of cyproheptadine should be considered (16) although its anti-serotonin properties in blunting HSF-induced encephalopathy in animals appears to require pre-challenge dosing.

Coroners would be well advised to complement their usual studies in cases of "SIDS" with well taken clinical histories including facts of antecedent viral illnesses and vaccination histories. Certain ancillary investigations such as HLA and insulin in clinical staged sudden death events of infants may provide further clarification of these clinical enigmas. Post mortem sampling for possible evidence of acute phase reactants must be drawn in such a fashion as to avoid postmortem artifacts (29).

Special clinical prudence in the use of the current DPT vaccine relative to atopic infants is suggested. All clinicians should be aware of the current discrepancies in contraindications followed abroad versus in the United States. Continuing clinical research and thus improved clinical reeducation should restore or reinforce the benefit-risk ratio attending the use of this potent, controversial vaccine during a time of high herd immunity and low natural disease incidence. It is further hoped that a model now being developed (23) may have potential for screening both the current whole cell and the newer acellular vaccine now undergoing field testing in the United States. Provisions contained in a recently introduced U.S. Senate Bill, S2117, the Hawkins-Hatch bill for compensation of vaccine victims, if fully implemented should do much to restore or maintain the confidence of parents and physicians alike.

Kevin C. Geraghty, M.D.

This paper is respectfully dedicated to the Resciniti and Ciotoli families of Broome County, New York.

The author appreciates the technical and emotional support of Constance Cunningham Geraghty.

TABLE 1

PT.#	DPT SERIES #	AGE @ RECEIPT OF DPT(OR DEATH)	INTERVAL POST DPT TO DEATH	MANUF., LOT	CLINICAL HISTORY PRIOR TO DPT	CLINICAL HISTORY AFTER DPT	CORONER'S CAUSE OF DEATH	CLINICAL CLASSIF. DEATH
1	#1	2 3/4 mos.	4 hrs.	A,1	Chronic rhinitis without fever, intolerant of milk-based formula; good health	Somnolent, floppy, cat-like cry in bursts	SIDS	NON-SIDS
2	#1	2 mos.	24 hrs.	B,?	Small for gestational age; good health, except for mild chronic colic	Excess somnolence, floppy during entire period; Temp. 101 shortly after vaccine.	SIDS	NON-SIDS
3	#1	3 mos.	3½ days	A or B, ?	Thriving except for chronic rhinitis without fever & mild chronic eczema	T 102 x 2 days; ongoing excessive somnolence; acted "drugged"	SIDS	NON-SIDS
4	None	(4½ mos.)	N/A	N/A	Good health	N/A	SIDS	SIDS
5	#1	2 mos.	8 days	C?,?	Good health	No significant rxn.	SIDS	SIDS
6	#1	3½mos.	30 days	?,?	Good health	No significant rxn.	SIDS	SIDS
7	#3	6 mos.	120 days	?,?	Good health	No problems noted; URI 2 weeks prior to death	SIDS	SIDS; post URI
8	#1	2 mos.	35 days	?,?	Good health	No problems noted after DPT; URI 2 weeks prior to death	SIDS	SIDS; post URI
9	#1	2½ mos.	24 days	A,?	Good health	No significant rxn; URI 2 weeks prior to death	SIDS	SIDS; post URI
10	None	(1½ mos.)	N/A	N/A	Good health; URI resolving prior to death	N/A	SIDS	SIDS; post URI

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Senator HAWKINS. Thank you very much, Mrs. Gary, for your moving testimony.

Mr. Kudabeck, would you tell your experience with this problem?

STATEMENT OF STEPHEN L. KUDABECK, JR., HOT SPRINGS, AR

Mr. KUDABECK. Senator Hawkins and members of the Committee on Labor and Human Resources, unlike the other two parents on this panel who have had their children either killed or damaged by complying with the mandatory vaccination program of their States, I don't yet have a vaccine-damaged child and I don't want one.

My name is Stephen Kudabeck. I reside in Hot Springs, AR.

My wife and I have six healthy, beautiful children who have never been vaccinated for anything, although it is the law in Arkansas that all parents who are not officially recognized as members of the Christian Science Church must have their children vaccinated for seven childhood diseases. My wife and I are not Christian Scientists. We do not intend to change our religion just to escape the penalties of this heinous law.

I view this battle not just as a man-to-man-type combat. There are two forces involved—the forces of good and evil. We have the God I worship versus the god of pseudoscience; the god of compulsion versus my God who gave me inalienable rights and responsibilities to protect my children.

We have been asked to voluntarily offer our healthy children as living sacrifices to a false god. The God I worship demands obedience rather than sacrifice.

I respectfully submit that there are many scientists and physicians who feel as I do. For some reason unknown to me, not a single one of these scientists or doctors has been invited or allowed to testify today in opposition to S. 2117. A partial list of these courageous scientists and medical doctors follows:

No. 1, Dr. Richard de Long, professor of biology at Del Mar College, Corpus Christi, TX. I respectfully request that his article in Science Digest and his recent letter to me be included as part of my written testimony. See my exhibit 4. Please add Dr. de Long's latest letter which is enclosed. Thank you.

Senator HAWKINS. Surely.

[Material supplied for the record follows:]

EXHIBIT 4 - p. 2

DEL MAR COLLEGE
CORPUS CHRISTI, TEXAS 78404

DEPARTMENT OF BIOLOGY

January 18, 1984

Mr. and Mrs. Stephen Kudabeck
107 Brandiles Lane
Hot Springs, AR 71913

Dear Mr. and Mrs. Kudabeck:

Thank you for your letter and the enclosed material.

I am very happy to know that there are people like you who are concerned about vaccinations and are intelligent and courageous enough to question their safety. I admire you for your perseverance and courage to actively defy the governmental mandates and to seek to obtain your fundamental rights. If I can be of any ehlp to you, please let me know.

I am well aware of the frustration of trying to educate the government and the medical profession on the subject of vaccines but they refuse to be enlightened. I have been trying since 1960 to do that. However, we should not surrender and should keep fighting against this most dangerous and dictatorial practice. Everyone should have the right to decide whether, or not, something foreign to their bodies should be introduced to their bodies. This is especially true if that something is hazardous as many vaccines are.

I have enclosed some material which shows some of the dangers of vaccination. I could supply you with more if you wish.

I hope you will be successful in your trial and, if you can, please let me know the result.

Best wishes,

Richard de Long

Richard de Long

dn

Enclosure

EXHIBIT A

OPPOSING COMPULSORY IMMUNIZATION

By Donna Kudabeck
Stephen Kudabeck

Editor's Note:

The authors and other Arkansas residents mentioned in this article were the subject of "Immunization Confrontations in Arkansas" by P.J. Spaul, an article in the December 1983 issue of Health Freedom News.

Our three school age children were suspended from a local public school district in Arkansas the first week in October 1983. Our letters requesting exemption from vaccinations were denied by the State Department of Health. The suspensions were for breaking the state immunization law.

We were not charged with breaking that law, however. We were charged with truancy when our children were not allowed back in school. The breaking of the one law automatically made us break another, for which we were then charged.

Stephen asked for a trial by jury on three separate occasions, but this was denied. Having to represent himself, he questioned the school principal and established in court these four points: 1) the children were indeed enrolled and attending school, 2) the Arkansas school had barred their entrance, 3) the children's records had been transferred to a school in Illinois (it was necessary to seek an alternative program for their educational needs during this time) and 4) if the children were brought back to school that day, the principal said they would not be allowed to attend.

The judge, without deliberation, pronounced Stephen guilty of *truancy* and fined him $750 plus court costs and appeal fees. We may now have the "privilege" of a trial by jury.

ALARMING PRECEDENT

The court, in our case and similar cases, cited a previous case that set the precedent in this state. This case came before the State Supreme Court in 1964. According to the decision of the Cude vs. State case, it was the opinion of the court that a failure to vaccinate, so as to enable a child to attend school, was a sufficient basis for finding for neglect. In that case the children, kicking and screaming, were taken away from the parents and given smallpox vaccinations.

In the Heard case (their children attended the same schools as ours did), the attorney who was substituting for our judge dropped the charge of truancy after a ten day deliberation; he said that it was evident that the school caused these children to be truant, not the parents. However, in his four page summary, it was his opinion that the state will have to go about vaccinating by the *approved* method of the case Cude vs. State and possibly provide a less cumbersome method for obtaining compulsory vaccination by legislative enactment. For the families involved, this was an alarming statement to read in the newspapers.

Even more alarming was a summons to appear in juvenile court which was received by the Cooks of Pine Bluff. The reason cited for being served was failure to take care of their child's medical and educational needs—CHILD NEGLECT.

Although they do not want their youngest child, Douglas, to have further vaccinations, these parents literally fought to get him in school. The two other children had reactions to the vaccines (which caused unnecessary medical expenses). Douglas had a response to the DPT vaccine as a baby. Four doctors, including Dr. Mendelsohn, agree the he should not have any more vaccinations; however, the state epidemiologist, Dr. Loefgren, does not agree with them and, in this state, his word is the final decision on all exemptions. (At the time of the printing of this issue, the Cooks were to appear in court where it would be decided whether Douglas will become a ward of the state and be vaccinated.)

MEDIA COVERAGE

When we moved from Illinois, little did we know what we would be facing. The papers have made it front page news. Channel 4, locally, interviewed us in our home; channels 4 and 7 were allowed in the courtrooms. We are finding, however, that the news coverage is staying within Arkansas!

Here in Arkansas recently, Channel 7 broadcasted two news segments, one week apart, dealing with the benefits and necessity of having infants and children vaccinated against DPT or DT, MMR and polio. One segment specifically focused on the benefits of the mump vaccine, which is not, as yet, a mandatory immunization of the state.

The media has given little attention to the flip side of the issue—the risks. Information on the risks associated with vaccines is scarce here. There has been no publicity given to vaccine-related lawsuits anywhere else in the U.S.

VACCINATION CONSENT FORM

Parents are given forms at the health department which they must sign (next to each vaccine to be administered). It states you have read the information regarding the vaccine, you have had the chance to ask questions and your questions were answered to your satisfaction. It then states that you understand the benefits and risks and that you "request" these vaccines be given to your child.

Why are these forms necessary when, no matter what you decide, there are only two choices—vaccination or prosecution? What choice is there? No shots, no school.

Do these forms release the health department, doctor, school board, etc., from the responsibility of damages?

Parents who have made the informed decision not to vaccinate their children face criminal prosecution and ultimately child neglect charges.

The mandatory age of school enrollment in Arkansas is 7. The pertussis vaccine is not required after age 7; however, there is a law on the books that states if a child has a sibling who has had an adverse reaction to the pertussis which resulted in a total, permanent disability, then that child is exempt from the pertussis vaccine, only. What a price to pay! It all boils down to parents being forced to use their child as a guinea pig to see if they are that one in a million statistic—to vaccinate one child to see if their other children will be affected.

INFORMED DECISIONS

All of the families involved in this issue are different; yet, they have all made informed decisions.

The Cook family has a history of reactions to vaccines, as well as a history of allergies and asthma.

The Heard family had chiropractic exemptions for their children due to a history of high fevers and asthma. The exemptions were reviewed and questioned in court after being on file for five years. Truancy charges were dropped; however, the children are still not allowed in school.

In another situation, a mother (of one daughter) objected on religious grounds. Even though a minister wrote a letter attesting to the mother's beliefs on the subject of immunization, the exemption was not granted since refusal to vaccinate was not a tenet of his church. The mother and daughter are now living out-of-state, because she is afraid of facing child neglect charges, while her husband continues to work here. This puts a great hardship on the family.

The most recent suspension is that of a 5-year-old boy who has a diagnosed liver disorder and an allergy to neomycin. The father is a chiropractor and feels that the shots would jeopardize the boy's health; the state epidemiologist once more disagrees. They have until the fall of 1985 to obtain an exemption or they, too, will be reported as truant.

As for ourselves, we have six beautiful children. We have been concerned with health all of lives. Five were born at home; all were nursed a long time. We have done much research over the years investigating both the benefits and the short-term and long-term risks associated with vaccines.

On both sides of our family there is a history of serious allergies, including allergies to medication and vaccines. There is also a history of lymphatic cancer, asthma, TB and heart disease. Based on our research, family history and personal beliefs, we felt a need for caution—so we made an informed decision not to vaccinate the children.

You may ask if we have attempted to contact the state legislators and have the law changed. Some parents did try to get the issue on the agenda of the last session, fall 1983, which lasted several weeks. The topic, quite appropriately, was education. However, they were told by the governor that the issue would have to wait until the next session convened. Meanwhile, more students are being suspended.

EXEMPTIONS

This is the first year that ALL exemptions are being reviewed, so more families could soon be questioned by the courts. There were 75 religious and 21 medical exemptions granted during the 1982-83 school year, according to the state epidemiologist.

No school is being overlooked in the search for unimmunized children. Publicity is focusing on the sensationalism of the courtroom scenes and suspended children, instead of searching for the facts behind the stories.

Editorials, written by some parents, applaud the actions of the health department and school boards for their stand in suspending students who may infect their children, children who have been vaccinated "by choice."

In most states, a doctor's recommendation is sufficient for an exemption—not so in Arkansas. At this time, even doctor's opinions are being questioned in court.

Twenty-one states allow for exemptions based on personal beliefs. In the other 29 states, parents are often forced into joining a new religion, literally hiding or facing criminal prosecution and publicly fighting in court, a most traumatic and expensive experience.

SUPPORT SOUGHT

As mentioned before, most of the media coverage is staying within Arkansas. Unless we can spread the news of these immunization confrontations, parents who object and have no choice, may well be swallowed up by the system.

Currently, new vaccines are being developed using a smallpox base. Various viruses or genes (from several disease-causing viruses through new genetic engineering procedures) are added to "protect" humans from everything under the sun. In view of this, the issue may eventually pertain not just to children, but to adults and the elderly as well. Are you ready to roll up your sleeve?

This is an important issue and affects so many people. We hope the time never comes when people calmly accept things, without question, simply because they are told, "It is for the good of all the people."

We have compiled a list of Immunization Information Sources; the list follows this article. If you have at your disposal research material on the DT, MMR or polio (orimune) vaccines, or case histories of reactions to these vaccines, and are able to send them to us, it would be greatly appreciated. Your help is needed! We would like to have as much information as possible to share with others.

Mr. and Mrs. Stephen Kudabeck
107 Brandiles Lane
Hot Springs, Arkansas 71913

EXhIBIT A 1

IMMUNIZATION INFORMATION

Parents' Guide to Childhood Immunization. This is a *free* booklet printed by the H.E.W. and can be obtained by writing to: U.S. Dept. of Health, Education and Welfare, Public Services, Center of Disease Control, Atlanta, GA 30333, or call (404) 329-3311.

The People's Doctor. Robert Mendelsohn, M.D., pediatrician, is the author of this timely medical newsletter. It is $24.00 for a one year subscription: The People's Doctor Newsletter, PO Box 982, Evanston, IL 60204, Dept. D-Jo. Be sure to request the following newsletters: Vol. 2, No. 4; Vol. 6, No. 10; and Vol. 7, No. 10. All of these newsletters deal with immunizations.

Mendelsohn Tapes. Modern Medicine and Immunization, Part 1, and Modern Medicine and Immunization, Part 2, are excellent tapes. They can be ordered through the National Health Federation, PO Box 688, Monrovia, CA 91016 for $7.95 plus $1.00 postage and handling.

Pertussis and Pertussis Vaccine: Information for Parents, Part 1. This 16 page booklet was put together by a nonprofit organization called Dissatisfied Parents Together (DPT). This organization is staffed by a handful of volunteer parents who send information on the pertussis vaccine to parents nationwide. The booklet is $3.00. Write to: Dissatisfied Parents Together, Box 563, 1377 K St., N.W., Washington, D.C., 20005. Phone (202) 543-4211.

DPT: Vaccine Roulette. This is a transcript of a WRC-TV broadcast in Washington, D.C., April 19, 1982 (8-9:00 PM). If you are not able to view this video yourself, it may be worth your while to read the transcript—especially if you have an infant or young children. You may request a transcript by sending $4.00 to: Tommi Williams, c/o WRC-TV, NBC, 4001 Nebraska Ave., N.W., Washington, D.C. 20016. (This video deals primarily with the pertussis part of the DPT vaccine and its potential risks. Lea Thompson also interviews some of the people that it has affected.)

Vaccination Condemned. The author of this 495 page book reveals some startling facts covering all facets of vaccines. It is available from Better Life Research, PO Box 42002, Los Angeles, CA 90042 for $12.50.

The Case Against Immunization. This is a new publication by Richard Moskowitz, M.D., a member of the American College of Home Obstetrics who has attended more than 400 home births. The book is available through the National Center for Homeopathy, 1500 Massachusetts Ave., N.W., Washington, D.C. 20005. Please contact the publisher for cost.

Vaccination—The Silent Killer. This book was written by Eleanor McBean, Ph.D., N.D., and Ida Honorof, publisher and editor of *Report to the Consumer* and winner of the National Health Federation's Media Award. This book presents many documented reports dealing with vaccines. For details on cost, please write to: Honor Publications, 2901 Los Flores Blvd., Lynwood, CA 90262, Dept. J.

Vaccination and Immune Malfunction. This new booklet was written by Dr. Harold Buttram, M.D., and John Chriss Hoffman. It can be ordered through Humanitarian Publishing Co., Quakertown, PA 18951. Two other publications on the subject are also available from the publisher: **How to Legally Avoid Unwanted Immunizations of All Kinds** and **The Dangers of Immunizations.** Please contact the publisher for details on cost.

Donahue Transcript #1222. This transcript is from a show on the subject of vaccinations—discussions of doctors and parents on the benefits and risks of vaccines. Send $2.00 to: Multimedia Program Productions, Syndication Services, PO Box 2111, Cincinnati, OH 45201.

Immunization Packet "Yes" or "No" This Packet of information was put together by Mrs. Jo Szczesny, an active member of the National Health Federation, I.A.C.V.F., and other health organizations. The packet is $12.00. Write to: Jo Szczesny, 3370 Sunset Trail, Northbrook, IL 60062, Dept. D.

A Maryland Health Department Report. J. Anthony Morris, Ph.D., formerly top virologist for the U.S. Division of Biological Standards, recently investigated a Maryland Health Department report of an outbreak of whooping cough. The report discloses some very interesting facts on how reports are obtained. The report is available from Dr. Morris, PO Box 40, College Park, Maryland 20740.

Transcripts of Congressional Hearings. The transcripts of the hearings held to investigate vaccines are available by writing Senator Paula Hawkins, c/o the Senate Office Building, Washington, D.C. The transcripts contain statements from people representing both sides of the issue, as well as parents of vaccine-damaged children. Request the transcripts from May 7, 1982 and July 22, 1983.

Citizens for Free Choice in Immunization—Wisconsin. This group of parents were responsible for getting information to the legislators of their state and, ultimately, for changing the law to allow parents to have a "free choice in immunization." Those who obtain the Donahue Transcript, **DPT —Vaccine Roulette,** will read about Marg Grant, who was instrumental in starting this group. Mrs. Grant has a child, Scotty, who was vaccine damaged 22 years ago after a DPT vaccine was administered. For those who wish to ask questions of her about her experiences or those who have a vaccine damaged child themselves, she would be more than happy to answer your letters and offer encouragement. You may write to her at the following address: Citizens for Free Choice in Immunization, c/o Mr. and Mrs. James Grant, 915 S. University Ave., Beaver Dam, WI 53916. Please enclose a self-addressed, stamped envelope.

The Governor's Letters. This material was presented by W. Gene Cretsinger, D.C., to Governor Ray of Iowa for his deliberation on the Iowa Mandatory Immunization Bill. This correspondence is now intended to provide scientific material to people to help them make an informed decision regarding immunization. Please write to: W. Gene Cretsinger, D.C., 4403 1st Ave., S.E., Suite #115, Cedar Rapids, IA 52402, or call (319) 393-9221. Please contact his office for cost.

Danger of Compulsory Immunizations: How to Avoid Them Legally. A Florida attorney has written this new booklet which provides easy to understand directions for parents who do not wish to have their children vaccinated. The booklet is available through Family Fitness Enterprises, Inc., PO Box 1658, New Port Richey, FL 33552 for $5.00.

The American Natural Hygiene Society, Inc. This organization is dedicated to the promotion of health and natural living nationwide. They have research material and other interesting information available on the subject of vaccines. Membership in the society is $20.00. Please be sure to mention that you would like to receive the information regarding immunizations. Write to: 698 Brooklawn Ave., Bridgeport, CT 06604, (203) 366-6229.

HFN

LEARN THE FACTS

The National Health Federation has prepared an Immunization Kit in response to numerous requests. This kit deals with school vaccination exemptions, compulsory immunizations, your right to refuse immunization in international travel, a report on ineffectiveness of measles vaccine, and the dangers of vaccination. To receive a copy of this kit, send $5.00, which includes postage and handling, to NHF, PO Box 688, Monrovia, CA 91016, or call (818) 357-2181. VISA and Master Card accepted.

EXHIBIT 1

some individuals or categories of injured individuals, and not others. DHHS has not issued a clear statement that explains its criteria for deciding when to allow some claims for compensation and not others.

In trying to resolve the issue of responsibility for the consequences of non-negligently caused, unavoidable vaccine injuries, the key question arising out of the swine flu experience would thus appear to be: Should the Government compensate injured vaccinees, and, if so, on what grounds? A clear delineation of the valuative criteria underlying any recognition by the Government of an obligation to provide vaccine injury compensation is an essential element of a compensation program. It is necessary in order to be able to assure those who are accorded compensation, those who are denied it, and the public at large, that compensation decisions have been made fairly rather than capriciously. A clear statement of principles is also the Government's best defense against a plethora of frivolous or invalid claims for compensation. One of the strongest critics of the swine flu compensation program compared it to a lottery. If this was the public perception of the program, then it is understandable that the program might have tended to attract "gamblers" who viewed themselves as having at least an outside chance to gain and nothing to lose by filing claims for compensation.

In the absence of a compensation system, DHHS is more or less locked into developing a legal defense around fulfillment of the "duty to warn." There is cause for concern, however, that this defense may not survive court challenges. First, as a practical matter, the "duty to warn" may not be satisfactorily discharged in mass immunization programs. A recent GAO Report tends to support this contention. GAO found that many vaccinees or parents of vaccinees have problems reading and understanding the forms:

> Even though vaccinees are required to sign the information statements or an accompanying card, we observed, local officials told us, and a CDC study showed that potential vaccinees may not read or understand the significance of the statements. Possible explanations for this are (1) apparent public disinterest in the content of the forms, (2) inadequate attempts by service providers to

EXHIBIT 2

IMPORTANT INFORMATION ABOUT MEASLES, MUMPS, AND RUBELLA AND MEASLES, MUMPS, AND RUBELLA VACCINES

WHAT IS MEASLES? Measles is the most serious of the common childhood diseases. Usually it causes a rash, high fever, cough, runny nose, and watery eyes lasting 1 to 2 weeks. Sometimes it is more serious. It causes an ear infection or pneumonia in nearly 1 out of 10 children who get it. Approximately 1 child out of every 1,000 who get measles has an inflammation of the brain (encephalitis). This can lead to convulsions, deafness, or mental retardation. About 2 children in every 10,000 who get measles die from it. Measles can also cause a pregnant woman to have a miscarriage or give birth to a premature baby.

Before measles vaccine shots were available, there were hundreds of thousands of cases and hundreds of deaths each year. Nearly all children got measles by the time they were 15. Now, wide use of measles vaccine has nearly eliminated measles from the United States. However, if children are not vaccinated they have a high risk of getting measles, either now or later in life.

WHAT IS MUMPS? Mumps is a common disease of children. Usually it causes fever, headache, and inflammation of the salivary glands, which causes the cheeks to swell. Sometimes it is more serious. It causes a mild inflammation of the coverings of the brain and spinal cord (meningitis) in about 1 child in every 10 who get it. More rarely, it can cause inflammation of the brain (encephalitis) which usually goes away without leaving permanent damage. Mumps can also cause deafness. About 1 out of every 4 adolescent or adult men who get mumps develops painful inflammation and swelling of the testicles. While this condition usually goes away, on rare occasions it may cause sterility.

Before mumps vaccine shots were available, there were more than 150,000 cases each year. Now, because of the wide use of mumps vaccine, the number of cases of mumps is much lower. However, if children are not vaccinated, they have a high risk of getting mumps.

WHAT IS RUBELLA? Rubella is also called German measles. It is a common disease of children and may also affect adults. Usually it is very mild and causes a slight fever, rash, and swelling of glands in the neck. The sickness lasts about 3 days. Sometimes, especially in adult women, there may be swelling and aching of the joints for a week or two. Very rarely, rubella can cause inflammation of the brain (encephalitis) or cause a temporary bleeding disorder (purpura).

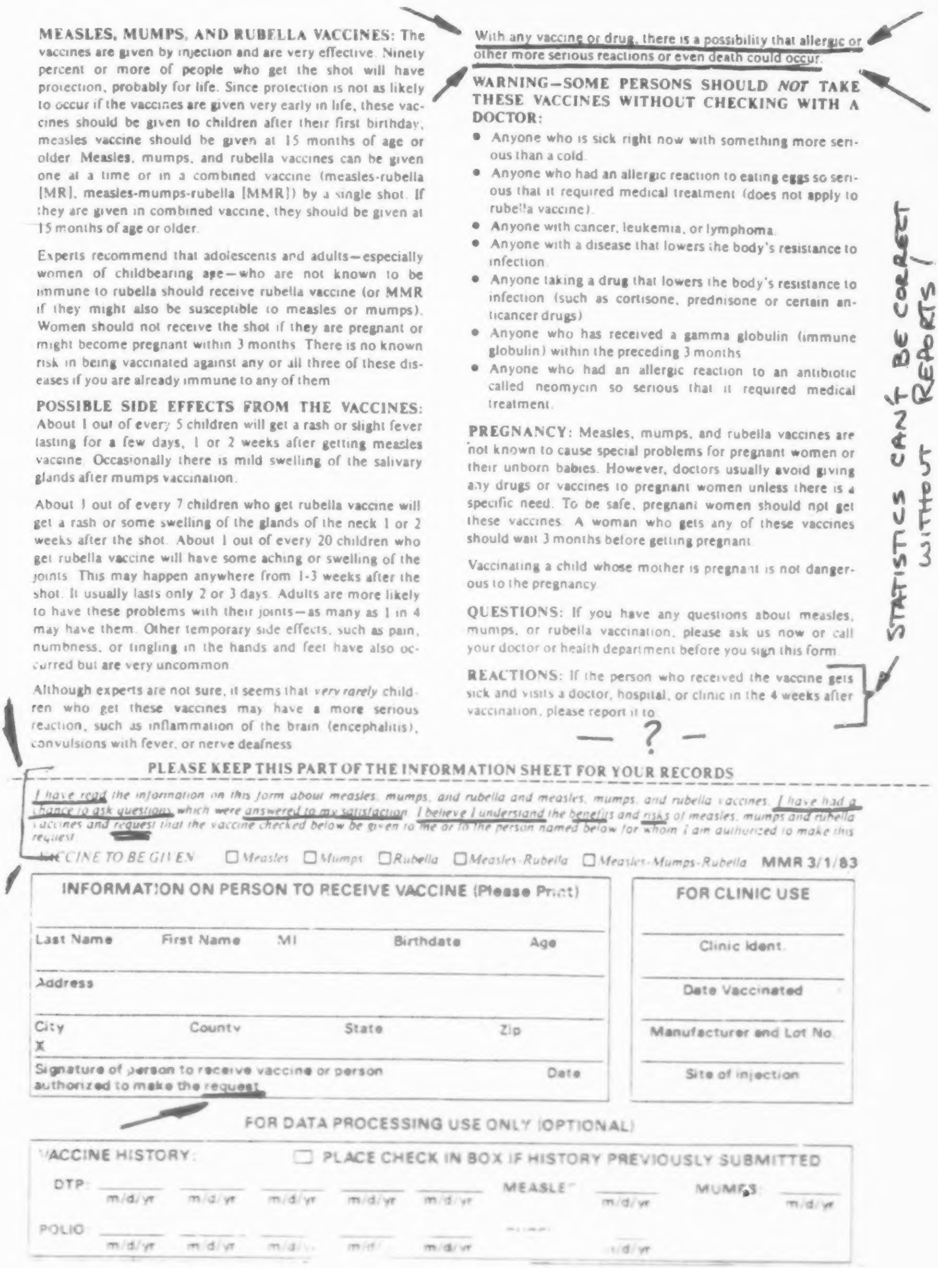
The most serious problem with rubella is that if a pregnant woman gets this disease, there is a good chance that she may have a miscarriage or that the baby will be born crippled, blind, or with other defects. The last big rubella epidemic in the United States was in 1964. Because of that epidemic, about 25,000 children were born with serious problems such as heart defects, deafness, blindness, or mental retardation because their mothers had rubella during the pregnancy.

Before rubella vaccine shots were available, rubella was so common that most children got the disease by the time they were 15. Now, because of the wide use of rubella vaccine, the number of cases of rubella is much lower. However, if children are not vaccinated, they have a high risk of getting rubella and possibly exposing a pregnant woman to the disease. If an unvaccinated woman later becomes pregnant and catches rubella, she may have a defective baby.

Since rubella is a mild illness, many women of childbearing age do not recall if they had rubella as a child. A simple blood test can show whether a person is immune to rubella or is not protected against the disease. Overall, about one in five women of childbearing age is not protected against rubella.

Please read this carefully

MMR 3/1/83



MEASLES, MUMPS, AND RUBELLA VACCINES: The vaccines are given by injection and are very effective. Ninety percent or more of people who get the shot will have protection, probably for life. Since protection is not as likely to occur if the vaccines are given very early in life, these vaccines should be given to children after their first birthday; measles vaccine should be given at 15 months of age or older. Measles, mumps, and rubella vaccines can be given one at a time or in a combined vaccine (measles-rubella [MR], measles-mumps-rubella [MMR]) by a single shot. If they are given in combined vaccine, they should be given at 15 months of age or older.

Experts recommend that adolescents and adults—especially women of childbearing age—who are not known to be immune to rubella should receive rubella vaccine (or MMR if they might also be susceptible to measles or mumps). Women should not receive the shot if they are pregnant or might become pregnant within 3 months. There is no known risk in being vaccinated against any or all three of these diseases if you are already immune to any of them.

POSSIBLE SIDE EFFECTS FROM THE VACCINES: About 1 out of every 5 children will get a rash or slight fever lasting for a few days, 1 or 2 weeks after getting measles vaccine. Occasionally there is mild swelling of the salivary glands after mumps vaccination.

About 1 out of every 7 children who get rubella vaccine will get a rash or some swelling of the glands of the neck 1 or 2 weeks after the shot. About 1 out of every 20 children who get rubella vaccine will have some aching or swelling of the joints. This may happen anywhere from 1-3 weeks after the shot. It usually lasts only 2 or 3 days. Adults are more likely to have these problems with their joints—as many as 1 in 4 may have them. Other temporary side effects, such as pain, numbness, or tingling in the hands and feet have also occurred but are very uncommon.

Although experts are not sure, it seems that *very rarely* children who get these vaccines may have a more serious reaction, such as inflammation of the brain (encephalitis), convulsions with fever, or nerve deafness.

With any vaccine or drug, there is a possibility that allergic or other more serious reactions or even death could occur.

WARNING—SOME PERSONS SHOULD *NOT* TAKE THESE VACCINES WITHOUT CHECKING WITH A DOCTOR:

- Anyone who is sick right now with something more serious than a cold.
- Anyone who had an allergic reaction to eating eggs so serious that it required medical treatment (does not apply to rubella vaccine).
- Anyone with cancer, leukemia, or lymphoma.
- Anyone with a disease that lowers the body's resistance to infection.
- Anyone taking a drug that lowers the body's resistance to infection (such as cortisone, prednisone or certain anticancer drugs).
- Anyone who has received a gamma globulin (immune globulin) within the preceding 3 months.
- Anyone who had an allergic reaction to an antibiotic called neomycin so serious that it required medical treatment.

PREGNANCY: Measles, mumps, and rubella vaccines are not known to cause special problems for pregnant women or their unborn babies. However, doctors usually avoid giving any drugs or vaccines to pregnant women unless there is a specific need. To be safe, pregnant women should not get these vaccines. A woman who gets any of these vaccines should wait 3 months before getting pregnant.

Vaccinating a child whose mother is pregnant is not dangerous to the pregnancy.

QUESTIONS: If you have any questions about measles, mumps, or rubella vaccination, please ask us now or call your doctor or health department before you sign this form.

REACTIONS: If the person who received the vaccine gets sick and visits a doctor, hospital, or clinic in the 4 weeks after vaccination, please report it to

— ? —

STATISTICS CAN'T BE CORRECT WITHOUT REPORTS!

PLEASE KEEP THIS PART OF THE INFORMATION SHEET FOR YOUR RECORDS

I have read the information on this form about measles, mumps, and rubella and measles, mumps, and rubella vaccines. I have had a chance to ask questions which were answered to my satisfaction. I believe I understand the benefits and risks of measles, mumps and rubella vaccines and request that the vaccine checked below be given to me or to the person named below for whom I am authorized to make this request.

VACCINE TO BE GIVEN ☐ *Measles* ☐ *Mumps* ☐ *Rubella* ☐ *Measles-Rubella* ☐ *Measles-Mumps-Rubella* **MMR 3/1/83**

INFORMATION ON PERSON TO RECEIVE VACCINE (Please Print)

Last Name	First Name	MI	Birthdate	Age
Address				
City	County	State	Zip	
X Signature of person to receive vaccine or person authorized to make the request			Date	

FOR CLINIC USE

Clinic Ident.
Date Vaccinated
Manufacturer and Lot No.
Site of injection

FOR DATA PROCESSING USE ONLY (OPTIONAL)

VACCINE HISTORY: ☐ PLACE CHECK IN BOX IF HISTORY PREVIOUSLY SUBMITTED

DTP:	m/d/yr	m/d/yr	m/d/yr	m/d/yr	m/d/yr	MEASLES:	m/d/yr	MUMPS:	m/d/yr
POLIO:	m/d/yr	m/d/yr	m/d/yr	m/d/yr	m/d/yr	[illegible]	m/d/yr		

EXHIBIT 2A

IMPORTANT INFORMATION ABOUT DIPHTHERIA, TETANUS, AND PERTUSSIS AND DTP, DT, AND Td VACCINES

Please read this carefully

DTP 3/1/83

WHAT IS DIPHTHERIA? Diphtheria is a very serious disease which can affect people in different ways. It can cause an infection in the nose and throat which can interfere with breathing. It can also cause an infection of the skin. Sometimes it causes heart failure or paralysis. About 1 person out of every 10 who get diphtheria dies of it.

WHAT IS TETANUS? Tetanus, or lockjaw, results when wounds are infected with tetanus bacteria, which are often found in dirt. The bacteria in the wound make a poison which causes the muscles of the body to go into spasm. Four out of every 10 persons who get tetanus die of it.

WHAT IS PERTUSSIS? Pertussis, or whooping cough, causes severe spells of coughing which can interfere with eating, drinking, and breathing. In the United States, more than 75 percent of reported pertussis cases occur in children younger than 5 years. Pertussis is a more serious disease in young children and more than half of the children reported to have pertussis are hospitalized. In recent years, an average of 1,700 cases of pertussis have been reported each year in the United States. Complications occur in a substantial proportion of reported cases. Pneumonia occurs in one of every four children with pertussis. For every 1,000 reported pertussis cases, 40 develop convulsions and 4 develop inflammation of the brain. In recent years, an average of nine deaths due to pertussis occurred each year.

Before vaccines were developed, these three diseases were all very common and caused a large number of deaths each year in the United States. If children are not vaccinated, the risk of getting these diseases will go back up again.

DTP, DT, AND Td VACCINES: Immunization with DTP vaccine is one of the best ways to prevent these diseases. DTP vaccine is actually three vaccines combined into one shot to make it easier to get protection. The vaccine is given by injection starting early in infancy. Several shots are needed to get good protection. Young children should get three doses in the first year of life and a fourth dose at about 18 months of age. A booster shot is important for children who are about to enter school, and should be given between their fourth and seventh birthdays. The vaccine is very effective at preventing tetanus—over 95 percent of those who get the vaccine are protected if the recommended number of shots is given. Although the diphtheria and pertussis parts of the vaccine are not quite as effective, they still prevent most children from getting a disease and they make the disease milder for those who do get it.

(PLEASE READ OTHER SIDE)

Because pertussis is not very common or severe in older children, those 7 years of age and older should take a vaccine that does not contain the pertussis part. Also, because reactions to the diphtheria part of the vaccine may be more common in older children, those 7 years of age and older should take a form of the vaccine that has a lower concentration of the diphtheria part. This vaccine which contains no pertussis part and a lower concentration of the diphtheria part is called Td vaccine. Boosters with the Td vaccine should be received every 10 years throughout life.

In addition, some children who are less than 7 years of age and have neurological disorders or who have had a serious reaction to previous DTP shots should not receive pertussis vaccine. A preparation called DT vaccine is available for them which does not contain the pertussis part.

The United States Public Health Service and the American Academy of Pediatrics recommend DTP vaccine be used in children up to 7 years of age unless they have had a serious reaction to earlier shots or have a neurologic disorder.

POSSIBLE SIDE EFFECTS FROM THE VACCINE: With DTP vaccine, most children will have a slight fever and be irritable within 2 days after getting the shot. One half of children develop some soreness and swelling in the area where the shot was given. More serious side effects can occur. A temperature greater than 102°F may follow 1 out of 20 DTP shots. Convulsions or episodes of limpness and paleness may each occur after 1 in every 1,750 shots. Unusual, high-pitched crying may occur after 1 in every 1,000 shots. Rarely, about once in every 110,000 shots, inflammation of the brain (encephalitis) may occur and permanent brain damage may occur about once in every 310,000 shots. Side effects from DT or Td vaccine are not common and usually consist only of soreness and slight fever.

WARNING—SOME PERSONS SHOULD *NOT* TAKE THESE VACCINES WITHOUT CHECKING WITH A DOCTOR:

- Anyone who is sick right now with something more serious than a cold.
- Anyone who has had a convulsion or other problems of the nervous system.
- Anyone who has had a serious reaction to DTP shots before, such as: a temperature of 105°F or greater; a convulsion; an episode of limpness and paleness; unusual high-pitched crying; or inflammation of the brain (encephalitis).

QUESTIONS: If you have any questions about diphtheria, tetanus, or pertussis or DTP, DT, or Td vaccination, please ask us now or call your doctor or health department before you sign this form.

REACTIONS: If the person who received the vaccine gets sick and visits a doctor, hospital, or clinic in the 4 weeks after vaccination, please report it to:

?

STATISTICS CAN'T BE CORRECT WITH OUT REPORTS!

PLEASE KEEP THIS PART OF THE INFORMATION SHEET FOR YOUR RECORDS

I have read the information on this form about diphtheria, tetanus, and pertussis and DTP, DT, and Td vaccines. I have had a chance to ask questions which were answered to my satisfaction. I believe I understand the benefits and risks of DTP, DT, and Td vaccines and request that the vaccine checked below be given to me or to the person named below for whom I am authorized to make this request.

VACCINE TO BE GIVEN: ☐ DTP ☐ DT ☐ Td

DTP 3/1/83

INFORMATION ON PERSON TO RECEIVE VACCINE (Please Print)

Last Name First Name MI Birthdate Age

Address

City County State Zip

x

Signature of person to receive vaccine or person authorized to make the request. Date

FOR CLINIC USE

Clinic Ident.

Date Vaccinated

Manuf. and Lot No.

Site of injection

FOR DATA PROCESSING USE ONLY (OPTIONAL)

VACCINE HISTORY: PLACE CHECK ☐ IN BOX IF HISTORY PREVIOUSLY SUBMITTED

DTP: m/d/yr m/d/yr m/d/yr m/d/yr m/d/yr MEASLES: m/d/yr MUMPS: m/d/yr

POLIO: m/d/yr m/d/yr m/d/yr m/d/yr m/d/yr RUBELLA m/d/yr

EXHIBIT 2B

IMPORTANT INFORMATION ABOUT POLIO AND ORAL POLIO VACCINE

Please read this carefully

OP 3/1/83

WHAT IS POLIO? Polio is a virus disease that may cause permanent crippling (paralysis) and occasionally death. There used to be thousands of cases and hundreds of deaths from polio every year in the United States. Because of the widespread use of polio vaccines, which became available beginning in the mid-1950's, polio disease has nearly been eliminated from the United States. Although thousands of cases continue to occur each year in the rest of the world, in the United States during the past 5 years there have been only 67 cases of polio reported, an average of 13 cases per year. Our success in preventing the spread of wild polio virus has been so great that most of the recent cases (approximately nine per year) have resulted from the rare side effects of oral polio vaccine (see below). Because of this fact, some people have asked why we should continue to use polio vaccine. The reason is that, even though we may not have much wild polio virus spreading here now, there is so much of it in the rest of the world that there is a great risk of its being reestablished if our children are not vaccinated.

ORAL LIVE POLIO VACCINE: Immunization with oral live polio vaccine (OPV) is one of the best ways to prevent polio. It is given by mouth starting in early infancy. Several doses are needed to provide good protection. Young children should get two or more doses in the first year of life and another dose at about 18 months of age. An additional dose is important for children when they enter school or when there is a high risk of polio, for example, during an epidemic or when traveling to a place where polio is common. The vaccine is easy to take and is effective in preventing the spread of polio. In over 90 percent of people, OPV gives protection for a long time, probably for life. Because OPV viruses live for a time in the intestinal tract of the person who is vaccinated, some of the viruses pass in the stool and can spread from the vaccinated person to those in close contact (usually household members). This may help to immunize these persons and is one of the advantages of OPV. The Immunization Practices Advisory Committee of the Public Health Service and the American Academy of Pediatrics recommend oral live polio vaccine as the preferred polio vaccine for people up to the 18th birthday.

POSSIBLE SIDE EFFECTS FROM THE VACCINE: OPV very rarely (once in about every 8.1 million doses of OPV distributed) causes paralytic polio in the person who is vaccinated. The risk may be slightly higher in adults being vaccinated and substantially higher in persons with abnormally low resistance to infection. Also very rarely (once in about every 5 million doses of OPV distributed) paralytic polio may develop in a close contact of a recently vaccinated person. Even though these risks are very low, they should be recognized. The risk of side effects from the vaccine must be balanced against the risk of the disease, both now and in the future.

(PLEASE READ OTHER SIDE)

PREGNANCY: Polio vaccine experts do not think oral polio vaccine can cause special problems for pregnant women or their unborn babies. However, doctors usually avoid giving any drugs or vaccines to pregnant women unless there is a specific need. Pregnant women should check with a doctor before taking oral polio vaccine.

WARNING—SOME PERSONS SHOULD NOT TAKE ORAL POLIO VACCINE WITHOUT CHECKING WITH A DOCTOR:

- Anyone with cancer, leukemia, or lymphoma.
- Anyone with a disease that lowers the body's resistance to infection.
- Anyone taking a drug that lowers the body's resistance to infection, such as cortisone or prednisone.
- Anyone who lives in the same household with anyone who has one of the conditions listed above.
- Anyone who is sick right now with something more serious than a cold.
- Pregnant women.
- Most persons age 18 and older because adults have a slightly bigger risk of developing paralysis from oral polio vaccine than children (However, if the risk of polio is increased-as may occur, for example, when there is an outbreak in your community-most polio experts recommend that unprotected persons receive oral polio vaccine regardless of age.)

NOTE OF INJECTABLE (KILLED) POLIO VACCINE: Besides the oral polio vaccine (OPV), there is also a killed polio vaccine (IPV) given by injection which protects against polio after several shots. This killed polio vaccine has no known risk of causing paralytic polio. Because OPV may provide lifetime protection, seems to provide stronger immunity in the intestinal tract (where infection first occurs), is simpler to administer, and is more effective in preventing the spread of polio virus than IPV, most polio experts feel that oral vaccine is more effective for controlling polio in the United States. Injectable polio vaccine is recommended for persons needing polio vaccination who have low resistance to serious infections or who live with persons with low resistance to serious infections. It may also be recommended for previously unvaccinated adults who plan to travel to a place where polio is common or for previously unvaccinated adults whose children are to be vaccinated with OPV. It is not widely used in this country at the present time, but it is available. If you would like to know more about this type of polio vaccine, or wish to receive this vaccine, please ask us.

QUESTIONS: If you have any questions about polio or polio vaccination, please ask us now or call your doctor or health department before you sign this form.

REACTIONS: If the person who received the vaccine gets sick and visits a doctor, hospital, or clinic in the 4 weeks after vaccination, please report it to:

?

STATISTICS CAN'T BE CORRECT
WITHOUT REPORTS!

PLEASE KEEP THIS PART OF THE INFORMATION SHEET FOR YOUR RECORDS

I have read the information on this form about polio and the oral vaccine. I have had a chance to ask questions which were answered to my satisfaction. I believe I understand the benefits and risks of oral polio vaccine and request that it be given to me or to the person named below for whom I am authorized to make this request.

OP 3/1/83

INFORMATION ON PERSON TO RECEIVE VACCINE (Please Print)				
Last Name	First Name	MI	Birthdate	Age
Address				
City	County	State	Zip	
x				
Signature of person to receive vaccine or person authorized to make the request				Date

FOR CLINIC USE
Clinic Ident.
Date Vaccinated
Manuf. and Lot No.
Site of injection

FOR DATA PROCESSING USE ONLY (OPTIONAL)

VACCINE HISTORY PLACE CHECK ☐ IN BOX IF HISTORY PREVIOUSLY SUBMITTED

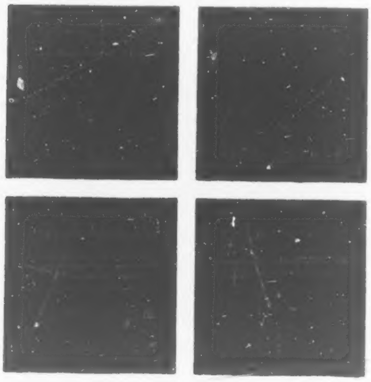
DTP	m/d/yr	m/d/yr	m/d/yr	m/d/yr	m/d/yr	MEASLES	m/d/yr	MUMPS	m/d/yr
POLIO	m/d/yr	m/d/yr	m/d/yr	m/d/yr	m/d/yr	RUBELLA	m/d/yr		

EXHIBIT 3

PARENTS' GUIDE TO CHILDHOOD IMMUNIZATION

- **MEASLES**
- **POLIO**
- **RUBELLA (German Measles)**
- **MUMPS**
- **DIPHTHERIA**
- **PERTUSSIS (Whooping Cough)**
- **TETANUS**

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service



DHEW Publication No. (OS) 77-50058
October 1977

A WORD TO PARENTS

as part of their routine immunizations.

Like most medicines, however, vaccines can cause side effects. These are usually mild—a slight fever, a sore arm, a mild rash—and of brief duration. But on rare occasion they are serious, which is why vaccines should be given only by physicians or other qualified health professionals.

The Public Health Service and the overwhelming majority of medical experts in this country and abroad believe that the benefits of complete immunization far outweigh the risks. The Service strongly recommends that all healthy children be immunized against all of the vaccine-preventable, childhood diseases. Are your children fully protected? If not, what should you do about it?

The decision to have your children vaccinated is yours, alone, to make. The purpose of this booklet, which discusses the things you should know about seven dangerous diseases and the vaccines that can prevent them, is to help you make that decision on the basis of accurate information.

Please read the material on the following pages and discuss any questions you have with your doctor or with the staff at the health department clinic. Learn all you can about the serious diseases of childhood. Then, make certain that your children are protected.

October 1977

EXHIBIT 4 -- 13 pages

There are many doctors, Ph.D.'s, biochemists, and other bonafide, medical scientists who have not had the opportunity to address the distinguished members of this committee; they have, nevertheless, done much research and investigation into the benefits and risks of vaccines, as well as the potential for latent effects. Following are just a few of the many quotes regarding vaccines that should be acknowledged and perhaps pondered upon, for these findings, too, can greatly affect the lives of our children and those of future generations.

GENETIC MANIPULATION

But an even greater threat exists to mankind from the use of vaccines. . .a threat that dwarfs even such problems as brain damage and crippling paralysis. It is the potential genetic damage and harm to the future of mankind that could result from the use of vaccines. Dr Richard DeLong, Professor of Biology at Del Mar College in Corpus Christi, Texas summarized his research in a letter which appeared in *Science News*, July 31, 1976:

". . . there are dangers. . . grave to the future of mankind which have been imposed inadvertently by entirely uncontrolled genetic manipulation during the last fifteen years or so. This uncontrolled genetic manipulation is the mass administration of attenuated viral vaccines to animal and human populations. Attenuated vaccine viruses are infectious, therefore they infect the recipients' cells and can do so in a number of ways. Attenuated vaccine viruses have the potential also to be transmitted vertically and these viruses then, could be inherited through generations. Some of the genes of these viruses may become integrated with the genomes of the recipients. The damage that could result in the future from such uncontrolled genetic manipulation could be incredible. This is to say nothing whatever of the other potential dangers the vaccine recipients must bear as the result of other aspects of vaccine viral infections such as mutations, chromosomal aberrations, birth defects, cancer, and reversion to virulence."

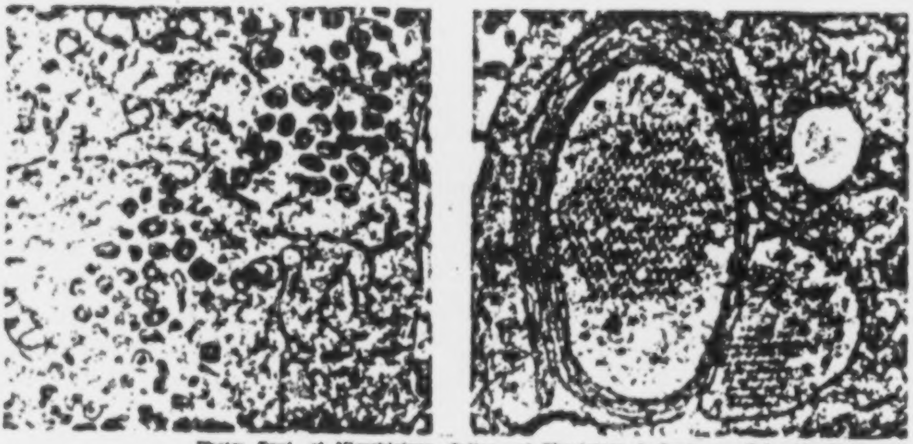


Photo: Dept. of Microbiology, College of Physicians & Surgeons, Columbia University

Vaccinia virus, left, and Adenovirus, right, magnified thousands of times here, are live viruses used in vaccinations or in tests. Both have produced some undesired effects.

Live virus vaccines—benefactors with a catch

No one denies that live viral vaccines have saved millions of lives and prevented other millions of people from being crippled for life. For public health, they have provided a control of disease unattainable otherwise. But there is another side of the story. Medical scientists do not know, in many instances, the long range—and sometimes immediate—effects that immunizing live viral vaccines will have on human cells. In a few cases, unusual effects are beginning to show up and suspicions are growing. Most distressing is the possibility that live viral vaccines may change the structure of living cells, including the hereditary material that is the fountainhead of life.

The author of this article, Dr. Richard DeLong, is an associate professor of biology at the University of Toledo. His research in the viral approach to human leukemia has revealed to him clues that impel him to sound an alarm. The views expressed in this article are his, based on his own studies, and represent one side of a subject vital to all.—Ed.

Richard DeLong, Ph.D.

SINCE we seem to be hurtling toward mass vaccination of the human population with live viral vaccines, the time is approaching when everyone should be made aware of the possible hazards involved in their indiscriminate use.

Usually, viruses are defined as

EXHIBIT 4 - p. 3

"replicating nucleoprotein macromolecules" that reproduce only within living cells. Nucleoprotein macromolecules are large molecules composed mainly of protein and nucleic acid. The nucleic acid is the hereditary material and this substance can reproduce itself in living cells. Viruses are molecular in size and can pass through most membranes very easily. They are intracellular parasites, limited for survival to this single life condition. When they infect, they maintain and reproduce themselves within living cells. Viruses are so intimately associated with the cells they infect that many times they incorporate their hereditary material into the hereditary apparatus of the cells.

Viruses "pluripotential"

Another characteristic of viruses is that they are "pluripotential," which means that they have the ability to manifest themselves in different ways, depending on environmental and cellular conditions.

Viruses have the ability to infect cells in two ways. One type of viral infection is called active; the other, latent. In active infection, viruses enter a cell and begin reproducing almost immediately. The new viruses are released from the cell and can infect others.

In latent infection, viruses enter a cell but do not begin reproducing immediately. Instead they apparently attach their hereditary material to that of the host cell's hereditary material. When the infected cell reproduces, so does the virus. In this manner, each cell formed from a virally-infected cell contains the hereditary material of the infecting virus. An appropriate stimulation from the environment causes the latent virus in the cell to become active, and it starts reproducing newly-formed viruses which are eliminated from the cell. All the stimuli which might induce a latent virus to become active are not known; some that are: radiation, heat, cold, certain chemicals.

Both active and latent viruses can act upon cells in different ways. There are at least three possible results when cells become infected with viruses—death of the cells, accelerated reproduction of the cells or no apparent effect. Cells which exhibit no apparent effect may be affected, however. There may be chromosomal defects or even more subtle defects which could be inherited by succeeding generations of cells. Chromosomes carry the genes or hereditary units, and any change in one or more of these units is inherited by the cell's offspring.

Viruses can be transmitted from generation to generation through the sperm or egg, the placenta and maternal milk.

Viruses used in live vaccines are no exception in all this.

Vaccines may be classified as of two types—live or killed. A live vaccine contains infectious viruses, though most of them are "attenuated," which means they have been changed to weaken or abolish their virulence for a particular disease.

A killed viral vaccine contains noninfectious viruses. Both confer protection on a vaccinated individual. However, the live viral vaccine stimulates the production of antibodies in humans causing a genuine viral infection in the individual. The killed vaccine stimulates antibody production without infection.

Some of the more important potential hazards of using live viral vaccines include the following: (1) damage or death to developing embryos, (2) possible cancer production, (3) possible initiation of new diseases, (4) possible genetic defects, (5) presence in the vaccines of "passenger" viruses which may be harmful.

It is well-known that some viruses can cause death or damage to developing human embryos if the mother becomes infected during pregnancy. The rubella virus is a classic example. This virus causes the "three-day measles" in postnatal life. In the developing embryo, it can cause abortion, death or many abnormalities. Some defects it has been known to cause include microcephaly (pin-headed idiocy), bone defects, deafness,

"Passenger" virus in action

Last November, federal authorities stopped the release of Sabin oral polio vaccine made since the previous July because green monkeys used in the manufacture of the vaccine in West Germany were identified as the source of "disease agents" apparently dangerous to man. Dr. Wilbur Downs, director of Yale University's Arbo-virus Research Unit, is quoted by *Medical World News* as saying, "Nothing like (the disease) has ever been seen before. It appears to be among the most dangerous agents known to man."

Investigators are trying to trace the whereabouts of 2,000 green monkeys used in making the U.S. embargoed lots of oral polio vaccine. Green monkeys from Uganda were identified as the source of the mysterious illness that struck 30 persons in West Germany, killing seven of them. Most of the Germans afflicted were laboratory technicans involved in obtaining monkey kidney tissue for culturing the polio vaccine viruses.

A spokesman for the division of biological standards of the National Institutes of Health, Bethesda, Md., confirmed reports that the embargo had been placed on the Sabin vaccine produced since last July. The agency added that supplies of the vaccine produced prior to July were in sufficient supply to meet all demands. The agency added that none of the green monkeys brought into the U.S. were from Uganda and the animals were in quarantine several weeks longer than the four-to-nine day incubation period for the so-called green monkey fever.

EXHIBIT 4 - p. 4

blindness, heart defects, dental abnormalities and many others. Vaccinia virus, the live virus used in vaccinating for smallpox, has been known to cause abnormalities or death in human embryos when the mother had been vaccinated during pregnancy. Recently, it has been found that the attenuated type II poliovirus (used in the Sabin live poliomyelitis vaccine) causes injury and death to cultured human embyronic cells.[1,2] The possibility exists then that viruses used in live viral vaccines could infect and affect embryos.

Cancer in animals

It is now established that certain viruses have the ability to cause cancer in some animals. As yet, no absolute proof has been found that viruses can cause human cancer, but evidence is accumulating that some viruses may. If this should be found to be true, then infectious viruses used in vaccines might also possess cancer-inducing properties. Live adenovirus vaccines are being developed for human vaccination. Adenovirus, type 12, a human respiratory virus now being used experimentally in vaccines for some respiratory ills (not flu), is known to cause cancer when injected into laboratory animals.

Viruses in live vaccines often are changed so that they will no longer cause the particular disease against which they are being used. During this changing process, however, the viruses may be changed in other ways. It is possible that these changes might, in some viruses, cause entirely new diseases in humans. Perhaps the most insidious unknown factor in the live viral vaccine picture, however, lies in the field of genetics.

Genetic defects are inherited. Viral infection can cause many genic and chromosomal changes in cells. If the germinal cells of humans became infected by viruses, they could cause genetic abnormalities in the sex cells of humans. Any defective sperm or egg would transfer its defects to the offspring. Viruses are known to cause chromosomal breaks, deletions, pulverizations, inversions and abnormal chromosomal numbers in cells. Any of these occurring in a sperm or egg could cause abnormalities in succeeding generations. The viruses used in live measles viral vaccine cause many chromosomal abnormalities in human cells. These have been found both in cells taken from vaccinated humans and from human cells in culture which were infected with the measles viruses used in the live measles vaccine.[3] Similarly, attenuated type II poliovirus, which is used in the live poliomyelitis vaccine, has been found to cause chromosomal abnormalities in cultured human cells.

The effects of live viral vaccines for any of the above mentioned potential hazards are seldom thoroughly tested. The United States Public Health Service does not require testing for any of these possible dangers.[4]

"Passenger viruses" are sometimes found in cells being used to cultivate viruses for vaccines.

The production of live viral vaccines requires a living cell system. It is possible that the cells used to cultivate viruses for vaccines may be infected already with viruses. These viruses are called "passenger viruses." Passenger viruses might be harmful to humans. The live poliomyelitis vaccine had been administered to many millions of people before it was discovered that the vaccine also contained a virus which was present in the monkey kidney cells that were used to cultivate the polio viruses for the vaccine. Since then, this virus, called Simian virus 40, has been found to produce cancer in laboratory animals, cause chromosomal abnormalities in cultured human cells and cause cultured human cells to be transformed to malignant cells.[5] So far such phenomena have not been observed in the human body—but that doesn't mean it can't happen.

A live mumps vaccine, which is in the experimental stage now but will be introduced on the market should human trials prove it effective in preventing mumps, is made by using live chicken cells. Chicken cells serve as hosts for the leukosis viruses. These viruses cause various forms of malignant diseases in chickens such as sarcoma, leukemia and osteopetrosis. So far, no proof exists that the same viruses can cause the same diseases in humans, but they are beginning to be suspected. The leukosis viruses are extremely common inhabitants of chicken cells and may be carried in chicken cells in the latent state.

Recently, Dr. Philip A. Brunell of New York University School of Medicine said there was some difference of opinion over duration of protection of the live virus mumps vaccine developed by a research team led by Dr. Maurice R. Hilleman of Merck Institute of Therapeutic Research. Dr. Brunell pointed out that natural mumps infection is believed to give nearly life long protection. If children receive a vaccine giving immunity for only several years, they might be susceptible again in young adulthood, when the illness can be most severe. The vaccine is expected to be on the market shortly after the first of the year.

It would be very difficult, if not impossible, to detect with certainty the presence of all latent viruses in cells. The live measles vaccine was made by cultivating the measles virus in chicken and dog kidney cells. It is known that many animal viruses can be transmitted to humans and cause diseases in humans. It behooves us then not to take chances concerning the possibility of transferring passenger viruses to humans through vaccination. Before the discovery of passenger viruses in the live poliomyelitis vaccine, no tests had been

EXHIBIT 4 - p. 5

made for these viruses in the production of live viral vaccines.

None of these dangers exist in killed viral vaccines. The rush to produce human vaccines containing live viruses is distressing to many virologists (there are many live viral vaccines in the experimental stage at the present time). A live viral vaccine should be used *only* if no effective killed viral vaccine can be developed. However, this has not been the case. Rather, live viral vaccines are being publicized and advocated for use over that of proven effective killed viral vaccines. Examples are the live Sabin poliomyelitis vaccine over that of the killed Salk poliomyelitis vaccine and the live measles vaccine over that of the killed measles vaccine. Instead of developing more live viral vaccines, efforts could and should — in the opinion of most thoughtful virologists—be applied to developing effective killed viral vaccines and administering these for vaccination.

It takes no genius to realize the far-reaching effects that these potential hazards could have on mankind should they exist, and *it has not been shown that they do not exist.* Perhaps mankind has been lucky, and the live vaccines administered already will not produce any ill effects in the human population. I hope so sincerely. Yet, this cannot be assumed since many of the effects of such vaccines may not appear for some time. Cancer and genetic defects, for example, may take years to appear. Some, such as birth defects, might have occurred already, and this should be investigated. The course that should be taken now is to stop introducing new live viral vaccines without adequate testing.

I am not against vaccination. In fact, I am one of the strongest advocates of vaccination and preventive medicine. My plea is simple—do not use live viral vaccines when effective killed vaccines are available.

The scientific and medical community, as a whole, and especially virologists, immunologists, geneticists, embryologists, cancer researchers, physicians and public health workers should be greatly concerned about live viral vaccination.

The public—largely uninformed on this subject to date—must be protected against unsafe or questionable vaccines. My appeal is to scientists and the medical profession to question the safety of live viral vaccination until they are utterly satisfied that no harm can come to mankind through its use.

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EXHIBIT 4 - p. 6

ON MANDATORY ATTENUATED VIRAL VACCINATION

The human body should be considered sacrosanct. No foreign substances should be introduced to a human's body without that human's consent. Vaccines are foreign substances to a human body and, thus they should not be made mandatory. To do so is wrong.

All vaccines are inherent with a certain amount of danger and the risks involved on whether to take a vaccine or not should be the decision of the intended recipient and no one else. Some vaccines are more dangerous than others and the most dangerous type of vaccine is the attenuated (live) viral vaccine. Attenuated viral vaccines are inherent with many very serious dangers.

I will list some of these dangers for you: (1) the vaccine viruses may revert to virulence and cause the very disease for which the vaccine had been meant to prevent, (2) the vaccines may be contaminated with other viruses and these viruses could cause disease, (3) the vaccine viruses could cause cancer, (4) the vaccine viruses could cause mutations, (5) the vaccine viruses could cause chromosomal aberrations, (6) the vaccine viruses could cause birth defects, (7) the vaccine viruses could cause new diseases.

Attenuated, or live, viral vaccines contain live, infectious viruses. These viruses infect the body's cells. They can infect cells in three different ways: (1) active infection, (2) masked infection and (3) latent infection. So, in reality, mandatory vaccination is forcing people to become infected with viruses without any choice on their part. These viruses can be transmitted from generation to generation in humans by a variety of ways: (1) through the human egg, (2) through the human sperm, (3) through the human placenta and (4) through human maternal milk. In effect, we are performing biological pollution of humans on purpose when we make people receive these vaccines. We are seeding not only the present generations but future generations, as well, with viruses of known and unknown potential harm. This may be unbelievable but it is true! Our knowledge of viruses and viral infection is so meager, at present, that we should proceed with great caution about anything involving viruses. Yet, we are blindly administering these viruses en masse to humans mandatorily. Any virologist, worthy of bearing that name, should know that infectious vaccine viruses are inherent with many dangers to a recipient. Such mandatory vaccination should be stopped immediately!

I have been critical of attenuated viral vaccination for the last twenty-four years and in those twenty-four years the knowledge and experience gained, during that time, has confirmed all of my fears about these vaccines.

At present, there are four attenuated viral vacines which are mandatory in most states of this country. They are required before children may enter public school. These vaccines are the attenuated poliomyelitis vaccine (Sabin), the attenuated measles vaccine, the attenuated mumps vaccine and the attenuated three-day measles (rubella) vaccine.

I will list for you some of the dangers in these vaccines. These are facts which we know now about these vaccines:

I. Sabin Vaccine (live polio vaccine)

1. It causes many mutations.
2. It causes many chromosomal aberrations.
3. It causes cancer in laboratory animals.
4. It causes cancer in cultured human cells.
5. It reverts to virulence.

6. It contained, at first, a contaminating virus called the SV_{40}. Many millions were infected with SV_{40}.
7. It kills human embryonic cells.

This is what is known now about SV_{40}.

1. It causes many mutations.
2. It causes many chromosomal aberrations.
3. It causes cancer in laboratory animals.
4. It causes cancer in cultured human cells.
5. It kills human embryonic cells.

II. Attenuated (live) Measles Vaccine

1. It causes many mutations.
2. It causes many chromosomal aberrations.
3. It causes cancer in laboratory animals.
4. It contains contaminating viruses (the leukosis viruses) which causes cancers in birds.

III. Attenuated (live) Mumps Vaccine

1. It causes mutations.
2. It causes chromosomal aberrations.
3. It is contaminated with leukosis viruses.

IV. Attenuated (live) Rubella Vaccine

1. It causes mutations.
2. It causes chromosomal aberrations.
3. One type of the vaccine can be contaminated with leukosis viruses.

EXHIBIT 4 - p. 9

4. It is not known that these viruses do not cause birth defects in humans because it has not been tested. Yet the very purpose of this vaccine is to prevent birth defects.

There is the possibility, also, that mandatory attenuated viral vaccination may be the cause of the surge in new diseases arising in the world. In the last twenty years about a dozen new diseases have arisen on this planet which never existed before in this world. The time of onset of these new diseases correlates well with the time of initiation of mandatory attenuated viral vaccination en masse to the public.

The fad of administering attenuated viral vaccines began in 1961 with the Sabin poliomyelitis vaccine and has continued unabated with many more attenuated viral vaccines being given since that time. The first new disease, called Reyes' syndrome, appeared in 1963. By this time, millions of humans had been vaccinated with the Sabin vaccine.

These new diseases may be the result of new viruses being produced in recipients' cells because of viral gene recombination occurring between two, or more, different viruses infecting the same cell. When this happens a different virus is created which will have different characteristics and, therefore, could have the ability to cause new disease. Some of the new diseases which have arisen within the last twenty years, in addition to Reyes' syndrome, are Lassa fever, non A-non B hepatitis, Ebola hemorrhagic fever, Kawasaki disease, Marburg disease and acquired immune deficiency syndrome (AIDS). Millions of humans are now harboring different vaccine viruses within their cells making it very probable that viral gene recombination can occur among these vaccine viruses and other infective viruses.

Only one of these dangers should be enough reason to ban attenuated viral vaccines. However, we have made these types of vaccines mandatory and are introducing them into the bodies of our children. It is appalling and incredible!

The damage that has been done to humanity already through the mass administration of attenuated viral vaccines is incalculable. This damage could result in genetic defects, malignancies, birth defects, new diseases and other, as yet, unknown damage.

It is imperative that mandatory attenuated viral vaccination be abolished. The answer, to damages caused by vaccination, is not to be found in insuring recipients of vaccines, because no amount of money can reimburse for illness or death, but by abolishing mandatory vaccination. The legislative bodies of this country should strive vigorously to enact a law abolishing the administration of all attenuated viral vaccines as soon as possible.

Thank you for giving me this opportunity to inform you of the dangers of vaccination. I am most grateful.

Richard de Long

Richard de Long, Ph.D.

Professor of Microbiology

Del Mar College

Corpus Christi, Texas

SUMMARY OF SERIOUS ADVERSE REACTIONS TO DTP
AS REPORTED IN FIVE RECENT U.S. STUDIES

	Reaction		
Study No	Crying/Screaming	Seizure	Hypotonicity/Hyporesponsiveness
1	0	0	0
2	591/1232 (48%)	0	0
3	4/253 (29%)	0	0
4	88/481 (18%)	1/481 (0.2%)	0
5	505/15752 (3%)	9/15752 (0.06%)	9/15752 (0.06%)

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EXHIBIT 4 - p. 11

HOW DO THE VACCINES WORK?

It is dangerously misleading and, indeed, the exact opposite of the truth to claim that a vaccine makes us "immune" or *protects* us against an acute disease, if in fact it only drives the disease deeper into the interior and causes us to harbor it *chronically,* with the result that our responses to it become progressively weaker, and show less and less tendency to heal or resolve themselves spontaneously.

By Richard Moskowitz, M.D.

What I propose is simply to investigate as thoroughly and objectively as we can how the vaccines actually *work* inside the human body, and to begin by paying attention to the implications of what we already know.

In particular, I would like to consider in detail the process of falling ill with, and recovering from, a typical acute disease, such as measles, in contrast with what we can observe following the administration of the measles vaccine.

We all know that measles is primarily a virus of the respiratory tract, both because it is inhaled by susceptible persons upon contact with infected droplets in the air, and because these droplets are produced by the coughing and sneezing of a person with the disease.

Once inhaled by a susceptible person, the measles virus then undergoes a long period of silent multiplication, first in the tonsils, adenoids, and accessory lymphoid tissues of the nasopharynx; later in the regional lymph nodes of the head and neck; and eventually, several days later, it passes into the blood and enters the spleen, the liver, the thymus, and the bone marrow, the "visceral" organs of the immune system.[1] Throughout this "incubation" period, which lasts from 10 to 14 days, the patient usually feels quite well, and experiences few or no symptoms.[2]

By the time that the first symptoms of measles appear, circulating antibodies are already detectable in the blood, and the height of the symptomatology coincides with the peak of the antibody response.[3] In other words, the "illness" is simply the definitive effort of the immune system to clear the virus from the blood. Equally noteworthy is the fact that the virus is eliminated by sneezing and coughing; i.e., via the same route through which it entered in the first place.

By "tricking" the body in this fashion (vaccines), we have accomplished what the entire immune system seems to have evolved in order to prevent; we have placed the virus directly into the blood and given it free and immediate access to the major immune organs and tissues, without any obvious way of getting rid of it.

It is evident that the process of *mounting* an acute illness like the measles, no less than recovering from it, involves a general mobilization of the entire immune system.

Such illnesses are in fact the decisive experiences in the normal physiologic maturation of the immune system as a whole in the life of a healthy child. For not only will the child who recovers from the measles never again be susceptible to it,[4] such an experience also cannot fail to prepare the individual to respond even more promptly and effectively to any infections he may acquire in the future. The ability to mount a vigorous acute response to organisms of this type must therefore be reckoned among the most fundamental requirements of general health and well-being.

In contrast, when an artificially attenuated virus such as measles is injected directly into the blood, bypassing the normal portal of entry, at most a brief inflammatory reaction may be noted at the injection site, or in the regional lymph nodes; but there is

Continued on page 18

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VACCINE

CONTINUED FROM PAGE 10

no "incubation period" of local contact at the normal portal of entry and, consequently, very little possibility of eliminating the virus via the same route.

Even more important is the fact that the virus has been artificially "attenuated," so that it will no longer initiate a generalized inflammatory response, or indeed any of the nonspecific defense mechanisms that help us to respond to infection generally. By "tricking" the body in this fashion, we have accomplished what the entire immune system seems to have evolved in order to prevent; we have placed the virus directly into the blood and given it free and immediate access to the major immune organs and tissues, without any obvious way of getting rid of it.

The result is, indeed, the production of circulating antibodies against the virus, which can be measured in the blood, but the antibody response now occurs as an isolated technical feat, without any generalized inflammatory response or any noticeable improvement in the general health of the organism. Exactly the opposite, in fact; the price that we have to pay for those antibodies is the persistence of virus elements in the blood for prolonged periods of time, perhaps permanently, which in turn presupposes a systematic weakening of our ability to mount an effective response not only to measles, but also to other acute infections as well.

Far from producing a genuine immunity, then, the vaccines may act by actually interfering with or *suppressing* the immune response as a whole, in much the same way that radiation, chemotherapy, and corticosteroids and other anti-inflammatory drugs do. Artificial immunization focuses on *antibody production*, a single aspect of the immune process, and disarticulates it and allows it to stand for the whole, in much the same way as chemical suppression of an elevated blood pressure is accepted as a valid substitute for a genuine *cure* of the patient whose blood pressure has risen. Worst of all, by making it difficult or impossible to mount a vigorous, acute response to infection, artificial immunization substitutes for it a much weaker, *chronic* response, with little or no tendency to heal itself spontaneously.

Far from producing a genuine immunity, the vaccines may act by actually interfering with or suppressing the immune response as a whole.

Moreover, adequate models already exist for predicting and explaining what sorts of chronic disease are likely to result from the chronic, long-term persistence of viruses and other foreign proteins within the cells of the immune system. It has long been known that live viruses, for example, are capable of surviving or remaining latent within the host cells for years, without continually provoking acute disease. They do so simply by attaching their own genetic material as an extra particle or "episome" to the genome of the host cell, and replicating along with it, which allows the host cell to continue its own normal functions for the most part, but imposes on it additional instructions for the synthesis of viral proteins.[5]

Latent viruses of this type have already been implicated in three distinct types of chronic disease; namely, 1) *recurrent or episodic acute diseases,* such as herpes, shingles, warts, etc.,[6] 2) *"slow-virus" diseases,* i.e., subacute or chronic, progressive, often fatal conditions, such as kuru, Creuzfeldt-Jakob disease, subacute sclerosing panencephalitis (SSPE), and possibly Guillain-Barre syndrome,[7] and 3) *tumors,* both benign and malignant.[8]

In any case, the latent virus survives as a clearly "foreign" element within the cell, which means that the immune system must continue to try to make antibodies against it, insofar as it can still respond to it at all. Because the virus is now permanently incorporated within the genetic material of the cell, these antibodies will now have to be directed against the cell itself.

The persistence of live viruses or other foreign antigens within the cells of the host therefore cannot fail to provoke *auto-immune* phenomena, because destroying the infected cells is now the only possible way that this constant antigenic challenge can be removed from the body. Since routine vaccination introduces live viruses and other highly antigenic material into the blood of virtually every living person, it is difficult to escape the conclusion that a significant harvest of autoimmune diseases must automatically result.

Sir Macfarlane Burnet has observed that the components of the immune system all function as if they were collectively designed to help the organism to discriminate "self" from "non-self"; i.e., to help us to recognize and tolerate our own cells, and to identify and eliminate foreign or extraneous substances as completely as possible.[9] This concept is exemplified not only by the acute response to infection, but also by the rejection of transplanted tissues, or "homografts," both of which result in the complete and permanent removal of the offending substance from the body.

If Burnet is correct, then latent viruses, auto-immune phenomena, and cancer would seem to represent different aspects of the same basic dilemma, which the immune system can neither escape nor resolve. For all of them presuppose a certain degree of *chronic immune failure,* a state in which it becomes difficult or impossible for the body either to recognize its own cells as unambiguously its own, or to eliminate its parasites as unequivocally foreign.

In the case of the attenuated measles virus, it is not difficult to imagine that introducing it directly into the blood would continue to provoke an antibody response for a considerable period of time, which is doubtless the whole point of giving the vaccine; but that eventually, as the virus succeeded in attaining a state of latency within the cell, the antibody response would wane, both because circulating antibodies cannot normally cross the cell membrane, and because they are also powerful immunosuppressive agents in their own right.[10]

The effect of circulating antibody will thereafter by mainly to keep the virus *within* the cell; i.e., to continue to prevent any acute inflammatory response, until eventually, perhaps under circumstances of accumulated stress or emergency, this precarious balance breaks down, antibodies begin to be produced in large quantities against the cells themselves, and frank autoimmune phenomena of necrosis and tissue destruction supervene. Latent viruses, in this sense, are like biological "time bombs," set to explode at an indeterminate time in the future."

Auto-immune diseases have always seemed obscure, aberrant, and bizarre, because it is not intuitively obvious why the body should suddenly begin to attack and destroy its own tissues. They make a lot more sense and, indeed, must be reckoned as "healthy," if destroying the chronically infected cells is the only possible way of eliminating an even more serious threat to life; namely, the persistence of the foreign antigenic challenge within the cells of the host.

Tumor formation could then be understood as simply a more advanced stage of chronic immune failure, according to the same model. For, as long as the host is subjected to enormous and unremitting pressure to make antibodies against itself, that response will automatically tend to become less and less effective.

Eventually, under stress of this magnitude, the auto-immune mechanism could easily break down to the point that the chronically infected and genetically transformed cells, no longer clearly "self" or "non-self," begin to free themselves from the normal restraints of "histocompatibility" within the architecture of the surrounding cells, and begin to multiply autonomously at their expense.

. . . what we have done by artificial immunization is essentially to trade off our acute, epidemic diseases of the past century for the weaker and far less curable chronic diseases of the present, with their amortizable suffering and disability.

A tumor could then be described as "benign," insofar as the breakdown of histocompatibility remains strictly localized to the tissue of origin, and "malignant," insofar as it begins to spread to other cell types, tissues, and organs, even in more remote areas. Malignancy might simply represent the reactivation of the virus from its latent phase into a more acute mode, albeit with less inflammation and more tissue destruction that the original wild-type infection.

If what I am saying turns out to be true, then what we have done by artificial immunization is essentially to trade off our acute, epidemic diseases of the past century for the weaker and far less curable chronic diseases of the present, with their amortizable suffering and disability. In doing so, we have also opened up limitless evolutionary possibilities for the future of ongoing *in vivo* (within a living organism) genetic recombination within the cells of the race.

Reprinted from the Journal of the American Institute of Homeopathy, "The Case Against Immunizations," which is available for $1.25 from the National Center for Homeopathy, 1500 Massachusetts Ave. N.W., Suite 41, Washington, D.C. 20005, phone (202) 223-6182.

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Mr. KUDABECK. No. 2, Dr. Robert Mendelsohn, formerly national director of Project Headstart, Medical Consultation Service, and chairman of the Medical Licensing Committee for the State of Illinois. Dr. Mendelsohn's three best-selling books, "Confessions of a Medical Heretic," "Male Practice: How Doctors Manipulate Women," and "How to Raise a Healthy Child in Spite of Your Doctor," establish him as a leading critic of compulsory vaccination programs in America.

No. 3, Dr. Anthony J. Morris, who was fired from the U.S. Food and Drug Administration for blowing the whistle on the swine flu fiasco.

No. 4, Dr. Kevin C. Geraghty, founder of Physicians for Study of Pertussis Vaccine.

No. 5, Dr. Richard Moskowitz, M.D., a leading homeopathic physician.

Madam Chairman and distinguished members of the committee, thank you for the opportunity to address this committee. The issue of compulsory vaccinations and the proposed compensation bill, S. 2117, are of great concern to me.

It has been said throughout the transcripts of the previous hearings and in the proposed bill, S. 2117, that Congress has found that there has been a longstanding effort to promote childhood vaccination by the Federal Government and to encourage States to adopt and enforce mandatory preschool vaccination laws. In the opening statements of the July 22, 1983, hearing you, Senator Hawkins, said that all 50 States have implemented legislation making immunization mandatory for school attendance. Because school attendance is required by law, parents must have their children immunized or face criminal prosecution. Refusing vaccination is difficult, if not impossible.

I am the father of six beautiful children. I well know the situation. I am addressing this committee not as a parent of a damaged child, but as a parent who is at this time being criminally prosecuted for not having my three school-age children vaccinated for school attendance. After attending school for 30 days last fall, they were barred from school and I was charged with truancy. See exhibits A and A1, "Opposing Compulsory Immunization."

My wife and I object to vaccines for reasons of personal beliefs, scriptural beliefs, and conviction of conscience. These beliefs have been longstanding, over 15 years. Our scriptural beliefs are our own, not that of a tenet of an organized religion.

When damages occur from vaccines, it is a most traumatic experience for a parent—heart rendering, to say the least. We have personally wept with parents who once had healthy, active children. Suddenly, after their child was immunized, they were faced with a child that had seizures, limpness, and once even death. As all too often happens, the doctors' reports did not link the child's injuries or death with the vaccines.

There are those whose children are not immediately disabled by vaccines. However, these parents have little chance of seeking compensation when the vaccine-related injury results in some degree of learning disability, arthritis, or other maladies that decrease the quality of life. The parents must accept the burden of special tutors or therapy. It becomes very difficult to link the causes of these injuries to vaccines.

Are these perhaps the frivolous lawsuits mentioned in the 1980 Office of Technology Assessment Report? See exhibit 1, "Compensation for Vaccine and Related Injuries," page 16, paragraph 2. I do not think any parent would call these lawsuits frivolous.

A compensation program has been discussed by the Government and drug companies since 1979. It was said that, because of the lawsuits brought against drug companies and other parties, where plaintiffs won large judgments against the drug manufacturers, the Office of Technical Assessment suggested that it may be desirable to establish a federally operated program to compensate vaccinees injured as a result of the public immunization program.

In the 1980 OTA technical memorandum, the informed consent forms—see exhibits 2, 2A, and 2B—were discussed. The assumption of the duty to warn was done at the insistence of the vaccine manufacturers who would not continue to produce for fear of liability.

S. 2117 addresses the need for better information to be disseminated to the parents and to encourage full discussion between the health provider, the one who administers the vaccine, and the parents.

On the "Important Information Forms" it states that one has had the opportunity to read the forms and ask questions to their satisfaction. It then states that you believe you understand the benefits and risks of the vaccines and that you request—I repeat request—that these shots be administered to your child. To request something means that you desire it.

What is the purpose of wording the form in this manner when a parent has no choice short of vaccination or prosecution? See exhibit 3.

Request implies that you have been able to make a decision. Duty to warn and informed consent imply that the recipient has a right to refuse. This is not the case, though. The OTA study of 1980 reports that getting the parents to take the time to read all the information on the forms has been a problem.

From our own experience, we have found that most parents do not read the forms because there is no choice. They have told us that, even though they question the safety of the shots and would rather not have their children get them, if they choose not to have the shots, they would end up in court, being publicized, ridiculed, or called a radical.

If any of you saw the documentary, "China's Only Child," on PBS networks, the same situation will ring a bell. A mother, 6 months pregnant with her second child, dearly wanted to keep her baby. However, without special permission, that becomes almost impossible. She and her husband were hassled and put before the block committee, and, finally, under duress, gave in to having an abortion. The mother, with tears in her eyes, letting us know full well that she did not want the abortion, was forced into signing a form saying that she requested that the abortion be performed. This story takes place in Communist China.

Our story takes place in a democratic society. Is there an urgency to provide better health forms and information sheets because the only way that an injured party can legitimately sue is if they can prove that the Government's warnings are inadequate?

This is what the OTA report states, page 2, paragraph 1. Informed consent and duty to warn imply that the potential vaccinees can refuse the vaccination. On page 17 of the 1980 OTA report it states:

> What is a more serious weakness in the Government's defense strategy is the contention that a properly warned vaccine recipient has assumed all risks of injury. Such an argument does not make sense, however, unless the vaccinee can refuse the vaccine. But vaccination is mandatory in many states for school entry [which itself is mandatory] and refusing vaccination in these cases is very difficult.

Are parents ever going to be given the right of a true, informed decision? Or, are we going to continue to sign those consent forms under coercion and duress to help the Government's defense strategy and perhaps our Nation's economy? Are we to continue to sign the consent form requesting the drugs under threat of criminal prosecution?

At this point the vaccination is not an issue of whether the vaccines are good or bad, not an issue of efficacy or safety, but it becomes an issue of basic human rights.

The fact that there is a compensation program being discussed shows that injuries are not that rare. The Comptroller General's report of June 1980 states that adverse reactions have been based on estimates and ball park figures. Clinical studies have been done on limited numbers.

Vaccines, in legal parlance, are known as unavoidably dangerous products. The FDA categorizes them as drugs. Yet, even though they are drugs, there is no personal prescription given to each and every child vaccinated. Instead, this medical belief is administered through legislative enactment and enforced through police power.

I am opposed to S. 2117. It, as well as any other compensation bill, no matter how it is stated, would have the same detrimental effect on people like myself. If the bill passes, the State has a remedy at law for the damage created by the vaccine, thereby strengthening the State's position for mandatory vaccination.

To save time of this committee, may I have my written testimony and exhibits made a part of the record?

Senator **Hawkins**. Surely.

Mr. **Kudabeck**. Thank you, Senator Hawkins.

Senator **Hawkins**. Thank you very much for helping us.

In answer to Mrs. Gary's question, why it was referred to the Labor Committee, the Labor Committee has jurisdiction over labor, health, education, employment, aging, handicapped, family and human services, alcoholism and drug abuse, the National Science Foundation, Legal Services, to mention a few. Health obviously is the reason we are here.

Mrs. **Gary**. Thank you.

Senator **Hawkins**. It may have some spillover into handicapped.

Mr. Schwartz—Jeff, you have really been fantastic in helping us with solving this problem. I really believe that you are another John Walsh in another problem. The cooperation of you and of the media—Lee Thompson took an active role in making this known to everyone, not just the people in this room, and I think that is what it takes to get the message out to the grassroots, so to speak, so the parents have the right to make that decision.

You stated in your testimony today that physicians are still not telling the contraindications to the proper authorities or to the parents of the pertussis vaccine. What proof do you have that this is true?

Mr. SCHWARTZ. Senator Hawkins, you have already heard some proof today from Donna Gary. I really want to commend her on her testimony. About two weeks ago we spoke about the possibility of my reviewing her draft testimony, since I am used to the way Washington operates and she isn't. I'm just very grateful that I didn't do that. I never saw her testimony or heard her testimony before today. I think her testimony could not be improved. Moreover, it sets forth several cases of failure to observe containdications.

Unfortunately, as I told you, we get lots of letters from parents whose children have been injured or even killed by the pertussis vaccine. These letters indicate and a number of court cases confirm, that there have been and continue to be, numerous cases of malpractice resulting from failure to observe the contraindications against administering pertussis vaccine.

With the Senator's permission, instead of going over the terrible details, I will simply submit for the record a letter which we submitted to the Academy of Pediatrics on December 5, 1983, documenting three court cases, decided cases or settled cases, and four letters, because we didn't want to overwhelm the AAP we could have sent many, many more than that—documenting instances in which contraindications that everybody agrees on were violated. We asked the Academy of Pediatrics to please notify their members, take the leadership in getting the message out that these contraindications must be observed; otherwise, potentially catastrophic results can occur. We would like to make this part of the record.

Senator HAWKINS. Surely.

[The letters referred to follow:]

Dissatisfied Parents Together News
Box 563, 1377 K St. N.W., Washington D.C., 20005

December 5, 1983

Dr. Harry Jennison
Executive Director
American Academy of Pediatrics
P.O. Box 1034
1801 Hinman Ave.
Evanston, IL 60204

Dear Dr. Jennison:

The purpose of this letter is to follow up on the request which we made in the course of our meeting on November 29, 1983, with Drs. Wehrle and Haggerty and yourself. Specifically, we asked that the American Academy of Pediatrics consider issuing a letter, advisory or bulletin (or adopting and disseminating a resolution or policy statement) to members of the Academy on the critical importance of scrupulous observation of the contraindications to administration of all vaccines, but particularly whole cell pertussis vaccines (such as the DTP vaccine).

We do not mean to presume to dictate the form by which the AAP should communicate with its members on this matter. We would respectfully request, however, that the communication be in writing and go to each member of the Academy. (We were pleased by the possibility, suggested I believe by either Dr. Wehrle or Haggerty, of a joint communication by the AAP and the AAFP to the members of both groups.) If possible, we would encourage similar communication to be prepared (perhaps by ACIP or ASTHO) for public health clinics, public health doctors and nurses who administer vaccines, although we recognize that the AAP has neither the authority nor the responsibility for vaccine policy in public clinics.

Specifically, we would hope that such a communication could include the following elements:

*listing of the contraindications now included in the Red Book and ACIP policy for each of the vaccines;

*urging physicians to be sure to take a thorough medical history before giving a child any vaccine;

*recommending that a sufficiently careful examination be conducted prior to each shot to assure that the child is not suffering from any current infection or illness;

*recommending that physicians advise the parents before the shots of the potentially serious reactions for which they should be alerted and be sure to question parents carefully about the possible occurrence of a contraindicating reaction to any previous vaccination; and *such other language as is necessary to assure that due caution is exercised by physicians in deciding whether to administer any additional vaccine after a potentially significant reaction to an earlier inoculation.

We recognize that our group differs with the AAP Red Book Committee on its current contraindications policies. We hope that future opportunity will present itself to discuss these concerns with the Red Book Committee. However, the purpose of the present request is not to seek a change in the list of contraindications to DTP vaccine. Rather, the purpose is to enlist AAP's active efforts to notify its members of the need for careful adherence to the current Red Book and ACIP contraindications.

Of course, not every vaccination in the face of a contraindication results in catastrophe. But as the material in Attachment #1 indicates, there have been such cases. Even one such result is too many, because this part of the DTP problem is avoidable. Yet as the illustrative excerpts from parents' letters to us in Attachment #2 indicate, some physicians, (perhaps many) appear to be unaware or unobservant of these contraindications, despite parents pleas for caution. We believe a strong effort by the AAP to bring this problem to the attention of its members would be a very positive step in the right direction. Hopefully, also, any such written notice could be distributed to our parents as well, thereby providing necessary consumer (as well as provider) education.

We appreciate your consideration of this request and would be pleased to work with the AAP on this effort, just as we have on the National Childhood Vaccine-Injury Compensation Act.

Sincerely,

Jeff Schwartz

Jeffrey H. Schwartz, President
Dissatisfied Parents Together (DPT)

cc: Dr. Paul Wehrle
Dr. Robert Haggerty

ATTACHMENT #1 -

SELECTED DECISIONS AND SETTLEMENTS IN CASES INVOLVING DTP VACCINATION IN THE FACE OF CONTRAINDICATING CONDITIONS

Wilson v. United States, U.S. District Court, N.D. Ga., No. C.A. C80-1325A, July 9, 1982 (infant received DTP inoculations at a U.S. immunization clinic from 1973 to 1975 . . . the shots were given by technicians . . . after the first shot, infant began jerking approximately once a day . . . the jerking increased after the second shot . . . after the third shot the jerking became more noticeable and frequent, the child's eyes rolled backwards and he began having infantile spasms . . . the fourth shot was given even though the child was on medication to prevent infantile spasms . . . as a result of his reactions to the pertussis component of the vaccine, the child now has an IQ of 50 . . . child and his mother brought an FTCA action against the US for failure to obtain her informed consent before giving the child the shots . . . mother was never informed that brain damage was a risk of the shots . . . district court ruled in favor of the child and awarded $2,570,000 including $1,860,000 for future institutional care; $610,000 for loss of future earnings; $45,000 for future medical expenses and $55,000 for past medical expenses . . . ATLA member William H. Schroder, Atlanta, Ga, represented plaintiff) (case was settled after trial . . . mother was awarded $350,000 . . . if child lives his normal life span he will receive $17 million)

Larson v. Eli Lilly, Mo., St. Louis Cir. Ct., 1974, 17 ATLA News L. 119 (April 1974) (3 month old healthy infant boy began series of DPT inoculations accompanied by oral poliomyelitis vaccine . . . no reaction to first injection . . . experienced a convulsion after 2nd injection one month later . . . 2 months later he received 3rd inoculation of one-half dosage DPT . . . developed high fever with convulsons that evening . . . now has a recurrent convulsive disorder . . . he brought action against pediatricians and drug mfr, alleging that warning on package insert was inadequate . . . warning stated that if reaction to any one dose was severe, the volume of subsequent doses should be reduced and additional injections given to complete the administration of the recommended total dose . . . plaintiff alleged that warning against any further inoculations should have been given since numerous articles in medical literature reported neurological complications following injection of pertussis vaccine in some infants and indicated that such complications should be considered a contraindication to further inoculation . . . defendants SETTLED for $150,000 . . . ATLA member C. Marshall Friedman, St. Louis, Mo., represented

Holcomb v. United States & Richardson - Merrell, U.S. Dist. Ct., S.D. W. Va. (filed in 1978, settled in Jan. 1982) (plaintiff infant was given first DPT shot in 1974 at U.S. health clinic in West Germany . . . she had "excessive screaming" reaction . . . no reaction to second shot . . . third shot given at U.S. army clinic in Virginia . . . plaintiff suffered post-pertussis encephalopathy . . . she brought suit against the United States and the mfr of the vaccine, alleging that the mfr was negligent in not including the excessive screaming reaction as a contraindication to further DPT shots in its 1974 literature and that the U.S. was negligent in not warning plaintiff's parents not to have further DPT shots given to her after she suffered this reaction and in failing to establish that she had a prior reaction before giving her the third shot . . . defendants SETTLED for $600,000 . . . ATLA member Monte Prieser, Charleston, W. VA., represented plaintiff)

ATTACHMENT #2

Letter #1 - dated 1/3/83

"I have a very big problem. . . . My pediatricians started my [twin] boys on their 1st D.P.T. shots on Friday, October 29, 1982 and on Monday, November 1st, 1982, the biggest of my boys started having seizures . . . . [The child] was in a mild coma and seizures for 48 hrs. I have asked all the doctors concerned in his case if the shot could have caused this. They tell me more than likely not, yet I feel they avoid my questions. . . . My biggest concern is my pediatrician is trying to get me to give [both twins] their second shot. I am terrified and don't know what to do. So could you please send me some information . . as soon as possible, I can't hold my doctor off without some wonder, but he's my child."

Letter #2 - dated 3/7/83

"About 5 days [after our son's second DPT shot] he started to have staring spells lasting 45 secs. to 2 minutes. He was admitted to the hospital, had a normal EEG and was discharged on Phenobarbitol. The seizures stopped. In June of 1981, he was due for his third shot & I again questioned the doctors reminding them of the problem [our son] had with seizures. Both the pediatricians and neurologist said the DPT shot had not contributed to his seizures. To satisfy me, they only gave him ½ of the third dose. Needless to say, 5 or 6 days later the seizures started again more severe, more prolonged and more frequent. He was hospitalized for 3 weeks and was having up to 60 focal motor seizures daily. He was transferred to the ICU when he eventually went into status seizures. . . .

"We brought him home on 5 types of medicine daily. He was sleeping 20 hrs/day and I felt we were losing him.

"I called the Mayo Clinic [and] after seeing [our son] and listening to our story they agreed with what we felt all along -- the DPT injections had contributed to the start of [our son's] seizure problems. They said there was no way of proving that but it was very likely the cause.

"My husband & I felt pangs of gult ever since. Why did I, especially since I am a nurse, allow him to get those DPT shot? But, more importantly, why did the doctors ignore me when I reminded them. . . [Our son] is still uncontrolled sometimes having 20-30 seizures per day."

Letter #3 - dated 3/1/83

"[Our son] was given his 1st DPT shot at 3½ months. I was told only that he might cry a little and be fussy. After 8 hrs. of high pitched crying I called Dr. He said it's the shot - nothing to worry about. [Our son] finally exhausted himself and fell asleep after 12 hrs. of crying.

"Second shot was given at 4½ mos. [July 1980]. Within 2 hrs. [he] had 105° temp. I called doctor - he suggested a warm bath. After the bath [our son] went into a grand [mal] seizure (5-10 min.) I didn't know what it was at the time. Called doctor - he said 'it was just a reaction to the shot. If he's ok now, don't worry.'

"Third shot - 5½ mos.

"Fourth shot - 18 mos. . .

"Our son is men. retarded, has microcephaly, C.P. & an oral motor problem so severe that he may never talk."

Mr. SCHWARTZ. Thank you.

Senator HAWKINS. I believe you were here at previous hearings when we heard testimony from the administration, as well as the Pediatrics Association, that they were now printing a warning and distributing that warning, signs to look for, and giving it to the parents prior to having the child inoculated. Obviously, that is not working universally.

Mr. SCHWARTZ. No, Senator Hawkins, it is not. The letters we receive continue to say, "Our doctor never told us that there was any risk." Even the stories at the public health clinics, where supposedly authorities are to distribute these totally inadequate information forms, parents sometimes don't get them. They are rushed into the thing. They don't get a chance to read them. They have no opportunity to discuss the information. Their children aren't even given exams of their ears and throats in many cases, I mean a simple physical exam to ascertain whether they are currently ill.

This system really can be made a lot safer just with the existing vaccine if we honor the contraindications that are there, if we examine our children, if we ask some questions. These simple safeguards have been and continue to be ignored all too frequently and everything has been assumed to be fine.

Senator HAWKINS. Could you discuss the vaccine injury table in S. 2117?

Mr. SCHWARTZ. Yes, Senator Hawkins. The vaccine injury table is a concept that either HHS has misunderstood or deliberately distorted. Now I know that they have high quality lawyers there and they are able to read legislation. So that raises an interesting question.

It is very clear that the vaccine injury table creates a presumption. If a parent can demonstrate—the parent has the burden of proof—that a child fits into the conditions of the vaccine injury table, then they would be entitled to compensation unless, by a preponderance of the evidence, the record demonstrates that there is another better explanation for the child's illness or disability.

When HHS says "incontrovertible evidence" would be required to show an alternative causation once a child fits within the conditions of the table, that is simply wrong. That is not what the bill says. I don't know where they got that, but that is not what the bill says. If they would read page 20 of the bill, they would see what the standard is in order to disprove a vaccine relationship

Also, if they want to know where we got this, the Academy of Pediatrics came up with the idea for a vaccine injury table initially. We met with them, and we said we like the concept of a presumptive table, so parents will know if they if their children will be eligible for compensation or not. We has some problems with the table that the AAP had initially devised because we didn't think it correctly reflect the medical literature. So we looked at the National Childhood Encephalopathy Study in England. I commend it to the Health and Human Services Department because they commended it to us. If they would read it again, they would find that it shows that statistically significant excess levels of convulsions with long-term consequences are occurring up to a week after the DPT immunization. That is what the study says.

Their own study, the UCLA study, funded by the FDA, shows a strong correlation with these kinds of reactions. Of course, the UCLA study didn't look at reactions occurring more than 48 hours after vaccination.

So when HHS says, "We don't know where we got this table," we got them from the places that HHS told us to consider. In fact, we got a lot of the data from an HHS report from the National Center for Health Statistics, called "Estimated Cost of Selected Medical Events Known or Suspected to be Related to the Administration of Common Vaccines," April 1981. This is an HHS report.

Why were they doing studies on the cost of compensation for events which don't occur?

Senator HAWKINS. Good question.

Mr. SCHWARTZ. Why haven't they read their own report? We didn't make this up out of thin air.

There would be no compensation if a child has not suffered permanent damage lasting longer than a year or hospital expenses of at least $2,500. That would have to be a pretty significant event, in light of what is found in the National Childhood Encephalopathy Study and their own study, the UCLA study—namely, a lot of parents don't even hospitalize their kids or bring their kids to a doctor when the children have a seizure. The parents may not even know what a seizure is because the doctors haven't informed them of what subtle neurological signs mean. So we are talking here of compensation only for pretty major events.

HHS poses a worst-case notion here. I mean, they really create a strawman in their testimony when they say, if all these children could come in, they could all get scads of money, lawyers' fees could added up, children could all get compensation for pain and suffering, and that is why we shouldn't pass the bill.

Well, if they would look at the safeguards of the bill, I think the safeguards are there to prevent the Treasury be looted. I think their real fear is that they know the truth. In their hearts they know the truth—there are many hundreds of children out there who will be entitled to compensation because they have been severely injured by these vaccines, and HHS doesn't want to admit that.

Senator Hawkins, if you will bear with me, I just want to read to you something from Science magazine that goes to the issue of HHS's willingness to admit the truth.

The article from Science says:

> Federal responsibility for the development of new vaccines is notably imprecise. Besides diffuseness of responsibility, the picture is also blurred by reluctance among vaccine workers to discuss problems openly when they arise. This is because of the understandable fear that public confidence in vaccines and vaccine authorities will be eroded.
>
> None of this implies that faults have been covered up or that the public has been conspired against in some kind of way, but there are dangers that problems will be de-emphasized in any system that discourages the fullest possible discussions, as some believe has been the case.
>
> For instance, a recent article on "Reactions with Viral Vaccines" says, "There has been a tendency on the part of certain higher government circles to play down any open discussion of problems associated with vaccines. Perhaps this has been overdone. Scientists now find themselves in the position of balancing benefits of a vaccine against the risk, yet are in no position to judge what the long-term risks are."

Then the article goes on to say that—

> The agency is failing in improving the quality of vaccines and assessing the longer-term risks and benefits associated with vaccine use.

It says:

> There has been curious inertia in seeking out or pursuing research data with implications for a regulatory decision. Specific research areas in which the coverage is most commonly faulted are the improvement of existing vaccines, particularly, among others, pertussis.

Now the thing that is most upsetting about this article in Science, Senator Hawkins, is that it was written in 1972. We are in 1984. Will we be here again, reading that we need a safer pertussis vaccine in 1996?

Senator HAWKINS. Not if it's up to me.

I have three cosponsors for this bill. Senator Hatch bravely cosponsored it, Senator Slade Gorton from Washington, and Senator Matsunaga—so that is 3 of all of the 100 Senators. A lot of them are waiting for the outcome, they tell me, of this hearing today, because there is some concern that, if we have compensation, we should not allow the parents to sue, also. They want that removed.

If this bill were enacted, in your opinion, Jeff, do you think some parents might switch to the compensation bill in lieu of the tort suit?

Mr. SCHWARTZ. I truly believe, Senator Hawkins, that there would be a number of parents who, if given the option, would choose to go the route of the compensation option. Parents who have children who are severely handicapped don't need the hassle of a lawsuit too. They don't need all the pain and delays and expense, et cetera. All that parents want to do is protect their kids. If they had a reasonably sure, reasonably simple, reasonably equitable, and reasonably inexpensive way to get compensation for their children, I think lots of parents would choose that, even though they might get less under that system than they might under the tort system. But parents will insist on their right to choose what is best for their children.

That is why we support the bill, even though it does not authorize punitive damages under the compensation system, even though it authorizes no pain and suffering for the parents, because the concern is for the children. Yes, I think many would switch. Yes, I think that would save money. Yes, I think that would in the long run be more just. But, again, the option to sue must be preserved.

Senator HAWKINS. Thank you.

You indicated in previous testimony before the committee that you had some correspondence written, answers to some questions that you submitted to HHS. I wonder if you could submit them for this record.

Mr. SCHWARTZ. We would be pleased to do so.

Senator HAWKINS. Thank you so much.

[Information supplied for the record follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Centers for Disease Control
Atlanta, Georgia 30333

July 20, 1983

Mr. Jeffrey Schwartz
Dissatisfied Parents Together
Box 563, 1377 K Street, NW
Washington, D.C. 20005

Dear Mr. Schwartz:

Enclosed are answers from CDC and FDA to questions 1-7, 10 and 11 and partial answers to question 9 contained in your letter of April 29. Because answers to questions 8, the remainder of 9, and 12 will require legal review, they will be submitted at a later date.

In its response to questions relating to pertussis vaccines and manufacturers, FDA has included information on the three licensed companies (Connaught, Lederle, & Wyeth) which are currently engaged in interstate commerce. Information on the Michigan and Massachusetts products is not included because, although they are also licensed, they are not distributing their DTP products for sale interstate.

Sincerely yours,

Walter R. Dowdle, Ph.D.
Director, Center for Infectious Diseases
and
Chairman, Interagency Group to Monitor
Vaccine Development, Production and Usage

Enclosures

1. PLEASE PROVIDE THE FOLLOWING INFORMATION WITH RESPECT TO EACH REPORT OF A POSSIBLE REACTION TO, SIDE EFFECT OF, OR COMPLICATION ARISING AFTER, THE ADMINISTRATION OF ANY VACCINE CONTAINING PERTUSSIS WHOLE CELL OR EXTRACTED MATERIALS, OF WHICH HHS DEPARTMENT (FDA, CDC, OR NIH) IS AWARE. . .

The monitoring system for illnesses following immunization operated by the Centers for Disease Control and the form on which illness is reported are described in Attachments 1-4. All forms received for the years 1979-81 have had identifying information removed and have been microfilmed. They are available at a cost of $25.20 from the Centers for Disease Control, Atlanta, Georgia 30333. These microfilms include most of the information requested in Question 1 with the exception of: State and locality in which vaccine was administered, nature of the licensure of the person administering the vaccine, number of pertussis inoculations received prior to this inoculation, and followup beyond 1 week. All reports at CDC 1979-1982 have been received on these forms which have been submitted through State health departments. 1982 forms are in process of being readied for microfilming; it is anticipated that they will be available before the end of this fiscal year. To our knowledge, reactions to DTP reported to CDC before 1978, are in the Federal Record Center and may be in labeled files although individual reports, letters, or memoranda may have been filed with other materials. To the best of our knowledge all reports made to State or local health departments of significant adverse reactions following DTP vaccination would have been reported to CDC or to the Office of Biologics, FDA. Information concerning adverse reactions to pertussis containing vaccines reported to FDA for the years 1977 through 1983 from a variety of sources are in Attachment 5.

2. WITH RESPECT TO "REPOOLING" OR "REWORKING" OF VACCINES CONTAINING PERTUSSIS WHOLE CELL OR EXTRACTED MATERIALS, PLEASE PROVIDE THE FOLLOWING INFORMATION:

   (a) A COPY OF RELEVANT FDA REGULATIONS, GUIDELINES, PROCEDURES, ADVISORIES, ETC, GOVERNING THE "REPOOLING" OR "REWORKING" OF SUCH VACCINES;

   (b) A BRIEF STATEMENT OF THE CONDITIONS UNDER WHICH "REPOOLING" OR "REWORKING" OF THE VACCINE IS PERMITTED UNDER CURRENT FDA REGULATIONS, GUIDELINES, ETC. AND OF THE LIMITATIONS ON "REPOOLING" OR "REWORKING" WHICH ARE IN EFFECT UNDER THOSE REGULATIONS, GUIDELINES, ETC,;

   (c) THE NUMBER OF TIMES A PERTUSSIS-CONTAINING LOT OR BATCH MAY BE "REPOOLED" OR "REWORKED" IN WHOLE OR PART;

There are no published regulations or guidelines which deal specifically with the "repooling" or "reworking" of pertussis vaccines. However each manufacturer has a specific internal procedure which he follows. Vaccines which have been "repooled" or "reworked" are assigned a new lot number. That lot is then subjected to all tests and procedures required for the release of a new vaccine lot. Those tests results are recorded in the product protocol and in the records retained by the manufacturer.

(d) THE MANUFACTURER'S NAME, BATCH AND LOT NUMBER FOR EACH PERTUSSIS-CONTAINING VACCINE WHICH HAS BEEN "REPOOLED" OR "REWORKED" AT LEAST ONCE, SINCE 1/1/50;

Information identifying vaccine lots that have been "repooled" or "reworked" is not held by the Office of Biologics, but is a part of the manufacturing record retained by the manufacturer.

(e) WHETHER "REWORKING" OR "REPOOLING" CAN UNDER SOME CIRCUMSTANCES RESULT IN THE VACCINE'S REACTOGENICITY OR NEUROTOXICITY INCREASING (AND, IF SO, THE CIRCUMSTANCES UNDER WHICH THIS MAY OCCUR).

There are no data of which we are aware to support the possibility that "repooling" or "reworking" can increase a vaccine's reactogenicity.

(f) THE MANUFACTURER'S NAME, BATCH AND LOT NUMBER FOR EACH PERTUSSIS-CONTAINING VACCINE WHICH FAILED EITHER THE POTENCY OR TOXICITY TESTS (OR BOTH) WHEN TESTED EITHER BY THE MANUFACTURER OR BY THE FDA (SINCE 1/1/50 - PRESENT).

All vaccine lots which are submitted to the Office of Biologics (OB) with a release protocol have passed all of the manufacturer's tests including those for potency and toxicity. Occasionally a manufacturer may submit a sample for concurrent testing at OB and at the manufacturing facility. Such lots are not considered for release until a protocol with all of the required information is submitted by the manufacturer. In some instances, concurrently tested lots are withdrawn by the manufacturer and not submitted with a release protocol. Data most readily available at OB are presented in Attachment 6, and include the manufacturer's name and lot number for each vaccine containing a pertussis vaccine component submitted with a release protocol that has failed the OB's tests for pertussis potency and/or toxicity since 1978. To provide data prior to 1978 would require a laborious search of records some of which are in storage in the Federal Records Center.

3. (a) PLEASE SUBMIT ONE COPY EACH OF ALL DOCUMENTS WHICH FORMED THE BASIS FOR INITIAL FDA LICENSURE DECISIONS WITH RESPECT TO EACH CURRENTLY LICENSED PERTUSSIS-CONTAINING VACCINE SOLD IN THE UNITED STATES. (IF THIS IS NOT POSSIBLE, PLEASE EXPLAIN WHY AND PROVIDE FULL CITATIONS TO THE RELEVANT DOCUMENTS.)

Copies of all documents which formed the basis for initial licensure decisions with respect to each licensed pertussis-containing vaccine currently sold in the United States are found in Attachment 7. It should be noted at the time of licensure of these DTP vaccines, some manufacturers obtained a license for each individual component of a combined vaccine, prior to filing a license application for the combined product. Therefore, we have enclosed a copy of the appropriate component's approval documentation to supplement the manufacturer's initial license approval for DTP.

(b) PLEASE SUBMIT ALL ADVERSE REACTION DATA SUBMITTED BY THE VACCINE MANUFACTURER (WHICH WAS REQUESTED TO PROVIDE SUCH DATA BY THE FDA) IN RESPONSE TO THE FINAL REPORT OF THE PANEL ON REVIEW OF BACTERIAL VACCINES AND TOXOIDS (AUG. 1979).

Attachment 8 responds to this request.

4. (a) PLEASE PROVIDE ALL INFORMATION WHICH TENDS TO SHOW WHETHER THE ELI LILLY COMPANY'S TRISOLGEN PRODUCT WAS MORE REACTOGENIC/NEUROTOXIC, LESS REACTOGENIC/NEUROTOXIC, OR ABOUT THE SAME AS WHOLE CELL PERTUSSIS-CONTAINING VACCINES.

Trisolgen is the trade name of a DTP adsorbed vaccine manufactured by Eli Lilly. The pertussis component of this product is an extracted, rather than a whole-cell, antigen. This vaccine was distributed from the early 1960's until the mid 1970's, at which time Eli Lilly ceased the manufacture of most biologics. There are few published studies of which we are aware in which this vaccine was compared to whole cell vaccines. In the report of Weihl et al., (Am. J. Dis. of Children 106: 124, 1963) there are data which indicate that children who received the extracted vaccine (Trisolgen) had fewer febrile reactions (defined by these investigators, as febrile responses greater than 0.5 degrees above normal) and fewer local reactions at the site of injection than did children given any of four different whole-cell vaccines. Serious neurological reactions were not described.

This product was reviewed by the Panel on Review of Bacterial Vaccines and Toxoids (see Final Report, Volume 1. August 1979, pp. 293-297). In their report, they state "in the matter of safety, the data give the general impression that the vaccine containing extracted pertussis antigen is somewhat less reactive than whole-cell pertussis vaccine in terms of local and minor systemic reactions. There is not sufficient basis to assume that this vaccine is any more or less safe than whole-cell vaccines in terms of the very low risk of serious encephalopathic reactions which accompanies the use of pertussis vaccines."

(b) PLEASE PROVIDE ALL INFORMATION ON THE REACTOGENICITY/NEUROTOXICITY OF THE WYETH LABORATORIES' EXPERIMENTAL PRODUCT USING THE LILLY PRODUCTION-EXTRACTION METHOD OBTAINED IN THE CLINICAL TRIALS OR OTHER STUDIES OF THIS PRODUCT.

Recently, experimental extract vaccines, simulating this type of acellular pertussis vaccine, were manufactured by Wyeth Laboratories. Clinical studies from two centers comparing two types of the DTP products containing whole cell vaccines were described by Brunell at a workshop on new pertussis vaccines (Brunell 1982) (Attachment 9). Data from one of these centers in 105 children were recently published by Murphy et al. (1983). The authors describe four "notable" reactions. Two children who received extract vaccines experienced episodes of irritability and screaming following the first immunization. These children were given subsequent injections and were reported to be developing normally one year after immunization. A third child receiving an extract vaccine had a temperature of 40°C (104° F) after the third injection. One child given whole-cell vaccine also experienced a temperature of 40°C and was found to have otitis media when examined the day after immunization. These workers reported that no child had a convulsion or shock-like episode. The results of studies with this vaccine performed at the second center and also presented at the workshop have not yet been published. These clinical trials have not demonstrated that the extracted vaccine products are clearly superior to the existing whole-cell vaccines.

(c) IN THE RONNEBERGER AND ZWISLER ARTICLE REFERRED TO BELOW (QUESTION 7a), THE AUTHORS STATE, "DPT-VACCINES WITH WHOLE BACTERIA AS THE ANTIGEN PRODUCED ENCEPHALOMYELITIS IN 57.9% OF THE LEWIS RATS AND 37.0% OF THE WISTAR RATS. AFTER INOCULATION OF EXTRACTED PERTUSSIS ANTIGENS, ONLY 16.4% OF LEWIS RATS AND 5.7% OF WISTAR RATS SHOWED NEUROTOXIC REACTIONS." (P. 182) THIS SEEMS TO SUGGEST THAT EXTRACTED PERTUSSIS VACCINES CAN BE LESS NEUROTOXIC TO MAN THAN WHOLE CELL VACCINES. IN LIGHT OF THIS INFORMATION, PLEASE EXPLAIN WHY YOU THINK THE WYETH EXPERIMENTAL PRODUCT CLINICAL TRIAL DATA DID NOT DEMONSTRATE THAT THIS EXTRACTED VACCINE WAS "SUPERIOR TO THE EXISTING WHOLE CELL VACCINE" FROM THE STANDPOINT OF POTENTIAL REACTOGENICITY/NEUROTOXICITY (ACCORDING TO DR. BRANDT'S JULY 21, 1982, LETTER TO REP. DAN MICA, QUESTION 15)?

Ronneberger and Zwisler reported on the ability of pertussis vaccines to enhance the antigenicity of guinea pig spinal cord, a foreign central nervous system (CNS) tissue, when injected into rats. Reaction against the injected CNS tissue resulted in an experimental allergic encephalomyelitis (EAE). This way of inducing CNS disease experimentally is not a new idea. Use of adjuvants along with neural tissues from a foreign species has been commonly used for many years to study EAE. The Ronneberger and Zwisler article did not deal with direct toxicity of a component of pertussis vaccine on the CNS. The EAE enhancing activity may or may not be related to other biological activity such as potential neurotoxicity. The reduced rate of late weight gain in the mouse weight gain test is the laboratory procedure which correlates with the clinical reactogenicity of pertussis vaccine [for further discussion, see response to question 5(a)]. In the discussion of their publication, Ronneberger and Zwisler state that "The recommended bioassay showed good correlation with the common toxicity tests performed with pertussis vaccines, such as the mouse weight gain test or the leukocytosis tests, and the increase of histamine sensitivity of mice." It is not clear that the procedure they have used has any advantage over the types of tests currently used world wide for this purpose. In addition, we should also note that the extraction procedure used by Ronneberger and Zwisler was not described in their article and it is therefore difficult to make a meaningful comparison between their extract vaccine and that produced by Wyeth.

Finally, as stated in our answer to question 4(b) above, the available clinical data do not support the suggestion that the Wyeth experimental pertussis vaccine was less reactogenic/neurotoxic than whole cell vaccine.

(d) HAS FDA DONE (OR IS FDA AWARE OF) ANY COMPARATIVE RISK-BENEFIT ANALYSIS OF WHOLE CELL PERTUSSIS VACCINES AGAINST EXTRACTED VACCINES? (IF NOT, WHY NOT? IS SUCH A COMPARATIVE ASSESSMENT PLANNED? IF SO, WHAT DID THE ASSESSMENT SHOW?)

See response to questions 4(a) and 4(b) above.

5. IN DR. PETRICCIANI'S NOVEMBER 17, 1982, LETTER TO BARBARA FISHER, VICE PRESIDENT OF DISSATISFIED PARENTS TOGETHER, THE STATEMENT IS MADE THAT, "THERE IS NO LABORATORY PROCEDURE WHICH IS ABLE TO EVALUATE A VACCINE'S TENDENCY TO PRODUCE ABNORMALLY HIGH FEVER, CONVULSIONS, COLLAPSE, EXCESSIVE SCREAMING OR POSSIBLE BRAIN DAMAGE." (PAGE 4)

a. PLEASE EXPLAIN HOW THIS STATEMENT CAN BE RECONCILED WITH (i) THE EXISTENCE OF THE PROPOSED ANIMAL ASSAY PROCEDURE RECOMMENDED FOR PRECLINICAL TESTING OF PERTUSSIS VACCINES IN RONNEBERGER & ZWISLER, "ALLERGIC ENCEPHALOMYELITIS IN RATS--TOXICITY ASSAY FOR PERTUSSIS VACCINES," FURTHER STUDIES IN THE ASSESSMENT OF TOXIC ACTIONS, ARCH. TOXICOL., SUPP. 4, 179-183 (1980); (ii) THE EXISTENCE OF EPA'S NEUROTOXICITY TESTING GUIDELINES UNDER SECTION 4 OF THE TOXIC SUBSTANCES CONTROL ACT; (iii) THE ANIMAL TESTING MODEL/PROCEDURES USED BY STEINMAN, ET. AL., IN "MURINE MODEL FOR PERTUSSIS VACCINE ENCEPHALOPATHY: LINKAGE TO H-2," NATURE, VOL. 299 (OCT. 21, 1982), PP 738-40; (iv) THE EXISTENCE OF THE "OTHER LABORATORY ASSAYS FOR WHOLE CELL PERTUSSIS VACCINE (INCLUDING) A TEST FOR MOUSE LABILE) TOXIN" WHICH ACCORDING TO THE ABOVE REFERENCED LETTER TO MS. FISHER, ARE REQUIRED BY THE JAPANESE GOVERNMENT: AND (v) THE NUMEROUS ANIMAL STUDIES OF FEBRILE SEIZURES, ETC. REFERENCED IN NELSON AND ELLENBERG, FEBRILE SEIZURES, NEW YORK: RAVEN PRESS (1981).

This statement was made because we are still unaware of any tests which are capable of predicting the ability of a vaccine to produce abnormally high fever, convulsions, collapse, excessive screaming, or possible brain damage. Many investigators have tried to define the components of vaccines which might be involved in eliciting such effects. It is known that the vaccine may contain a variety of biologically active substances, such as endotoxin (as do other vaccines derived from gram negative bacteria) and LPF. A variety of procedures have been utilized in many laboratories in an attempt to evaluate the "toxicity" of pertussis vaccines. Several of these tests were used in a recent report by Hooker (J. Biol. Stand. 9: 493-506, 1981). She concluded that based on her evaluation the "seven day weight gain test and the hyperinsulinemia test appeared to be the most sensitive to differences between vaccines." As you know, a mouse weight gain test has been used for measuring the "toxicity" of vaccines in some laboratories for many years. This type of assay is in use in the U.S. Some workers have shown that vaccines which are more reactive in this assay are associated with more reactions in children, but others have found no such relationship (reviewed by Hooker). This assay is often considered to be measuring the mixtures of toxic materials which may be produced by B. pertussis, including endotoxin and LPF, and it is assays of this type that are used throughout the world by biologics control agencies.

(i). The paper by Ronneberger and Zwisler (1980), as stated in our response to question 4(c), extends the observations previously made by many workers to show that pertussis vaccines when injected along with foreign central nervous system tissue, such as spinal cord, elicit an allergic encephalomyelitis (EAE). As indicated above, these workers have reported that when the neurotoxic activity, as defined by EAE, was compared to the toxicity of a vaccine as evaluated by a mouse weight gain or histamine sensitizing assay, good correlation between tests was obtained. Although this type of assay has been proposed as a tool for assessing the toxicity of pertussis vaccines, we are unaware that any data are available to correlate the results of such a bioassay with the ability to predict the ability of a vaccine to induce neurologic reactions in infants. The correlation of such an assay with neurological events considered to be rare in number would be very difficult to establish.

(ii). The EPA neurotoxicity testing guidelines relate to techniques for developing data on morphologic changes in the nervous system for chemical substances and mixtures subject to such testing under the Toxic Substance Control Act (TOSCA). The types of tests included in these guidelines were specifically tailored to the assessment of toxic substances defined in the Act and are not directly transferable for the purpose of testing pertussis vaccines for their ". . . tendency to produce abnormally high fever, convulsions, collapse, excessive screaming or possible brain damage".

On the other hand, recent research with biological toxins has utilized more specific and sensitive studies at the cellular, subcellular, and molecular levels. Such studies may permit a better understanding of the physical and chemical nature of a toxin, its interaction and effect on host target tissues and eventually may allow the design of specific tests for such toxins. However, it would be necessary to show that such tests correlate with clinical reactions before they would be considered for routine use in control testing of pertussis vaccines.

(iii). The paper by Steinman et al is of course of great interest. However, as indicated in our comments above, we are not aware that any correlation has yet been made between the observations, and the ability of a vaccine to induce severe reactions in children. These authors suggest that their model may provide insight into the pathogenesis of immunization-induced neurological complications. We will be following this work with great interest. However, it should be pointed out that the most effective method for solving the problem of serious adverse reactions probably lies in the development of improved vaccines. (See also our response to question 5(b) below).

(iv). As discussed above, many different laboratory assays have been proposed for evaluating toxicity of vaccines, and different control laboratories in different countries may use different procedures. WHO has recognized (see Requirements for Pertussis Vaccine, Thirtieth Report WHO Expert Committee on Biological Standardization. A.3.4.5. Toxicity Test. 1979) that no single test has been developed which can predict untoward reactions.

The mouse weight gain test is a procedure that assesses the overall effects of endotoxin, LPF, and dermonecrotic toxin. The Japanese government does require other assays for pertussis vaccines which are not required in the United States and we are not aware these are a routine requirement of any other national control authorities testing of pertussis vaccine. Those additional tests done in Japan include a test for mouse-leukocyte increasing toxicity and a test for dermonecrotic (heat labile) toxin. At the time a product license is approved in the United States, evidence is presented to show that the method for inactivation employed by the manufacturer inactivates the dermonecrotic toxin of pertussis vaccine. Pertussis vaccines marketed under U.S. license do not contain biologically active dermonecrotic toxin and this is checked by the absence of early deaths in the mouse weight gain tests done on each vaccine lot. The mouse leucocyte-increasing toxicity test done by the Japanese measures the biological activity of LPF. This activity is measured by the reduced rate of late weight gain in the mouse weight gain test.

(v). The experimental systems described in Febrile Seizures relate to the artificial induction of hyperthermia in animals, and the assessment of subsequent seizures and pathological lesions. We are not aware of information to suggest that if pertussis vaccines were used in those or other animal tests, that any of them could predict the ability of a vaccine to produce abnormally high fever and seizures in humans. As pointed out by Dr. Vannucci in Febrile Seizures,

> "In addition, it is clear that what we do by inducing seizures with fever in animals is vastly different from the situation in human beings, simply because many children manifest their seizures with fever at temperatures much lower than those at which we are able to obtain seizures in animals. Even in the youngest and most susceptible animals, one must induce temperatures well above those seen in the clinical setting.
>
> "Unfortunately, animals do not usually show us a graded range of biological variation in response to different levels of heat. Each species and age seems to develop seizures at a specific level of temperature. Further, seizure-susceptible, inbred strains are vulnerable only to specific stimuli: audiogenic, seizure-susceptible animals do not have seizures easily with fever. So as yet, we do not have a good experimental model of febrile seizures in the animal situation."

The use of limited resources for the development and clinical testing of improved vaccines would seem to be a more productive approach than to divert those resources into research on an animal model for febrile seizures. However, if a test is developed for febrile seizures which does provide good correlations with the human clinical situation, it would be evaluated with respect to its usefulness in testing current or new pertussis vaccines

(b) WHAT RESEARCH, DEVELOPMENT, OR OTHER STUDIES ARE CURRENTLY BEING CONDUCTED BY, SUPPORTED BY, OR PLANNED BY HHS (FDA?, CDC? NIH? OTHER?) TO DEVELOP AN ANIMAL TEST PROCEDURE WHICH CAN BE USED EFFECTIVELY AS A PRELINICAL SCREENING MECHANISM TO DETECT VACCINE LOTS WHICH TEND TO BE MORE NEUROTOXIC/POTENTIALLY REACTOGENIC?

The agency uses animal models such as lymphocytosis in mice and histamine sensitization in its evaluation of purified antigens and in its experimental programs of evaluation of LPF antigen content of vaccines (see transcript of Workshop 1982). These assays are being used to evaluate the bioactivity of antigens which might be considered protective antigens.

The work of Steinman et al., was supported in part by an NIH grant (NS 18235-01). Researchers from England have begun studies of children who develop complications from pertussis vaccine. They hope to identify a genetic marker in humans which may help to identify a subpopulation of children who are at greater risk to reactions to the vaccine. The feasibility of conducting retrospective or prospective HLA studies in humans in the United States is under review by NIAID.

(c) WHAT CURRENT PLANS DOES HHS HAVE TO REQUIRE LICENSED MANUFACTURERS TO UTILIZE ONE OR MORE LABORATORY TEST PROCEDURES FOR EVALUATING A PERTUSSIS VACCINE'S POTENTIAL NEUROTOXICITY/REACTOGENICITY (OTHER THAN THE MOUSE WEIGHT GAIN PROCEDURE WHICH ADMITTEDLY IS INADEQUATE FOR THE ABOVE PURPOSE)? WHAT CURRENT PLANS DOES HHS HAVE TO CONDUCT SUCH TESTING ITSELF?

See comments under (a)(iv) above. At the present time, HHS has no plans to require licensed manufacturers to include additional tests for licensed whole cell vaccines.

As new scientific information is developed, FDA would consider performing additional assays on licensed products, and if there were a consensus that they were meaningful, they would be proposed as new requirements.

6. IN DR. PETRICCIANI"S LETTER TO MS. FISHER REFERRED TO ABOVE, THE ANSWER TO QUESTION 21 WAS AS FOLLOWS: TITLE 21 OF THE CODE OF FEDERAL REGULATIONS, SECTION 211.198 REQUIRES THAT MANUFACTURERS HAVE WRITTEN PROCEDURES DESCRIBING THE HANDLING OF WRITTEN AND ORAL COMPLAINTS. BOTH THE OB AND THE CENTERS FOR DISEASE CONTROL RECEIVE REPORTS OF ADVERSE REACTIONS. THE NATURE OF THEIR RESPONSE IS BASED ON AN EVALUATION OF THE REPORTED REACTIONS."

(a) PLEASE PROVIDE A COPY OF EACH OF THE WRITTEN PROCEDURES ADOPTED BY WYETH, LEDERLE, AND CONNAUGHT IN CONFORMANCE WITH 21 CFR 211.198.

The provisions of 21 CFR 211.198 are part of the Good Manufacturing Practices for Human and Veterinary Drugs with which manufacturers of licensed biological products must comply. It was the intent of the agency when these regulations were promulgated to provide manufacturers with as much latitude as possible for efficient review of the drug product complaints. Thus, the manufacturers are responsible for the development of their own internal written standard operating procedures in conformance with the requirements of 21 CFR 211.198. Manufacturers are not required to submit copies of their written procedures for handling oral and written complaints.

(b) WERE THESE PROCEDURES REVIEWED AND APPROVED BY FDA? (IF SO, WHEN? IF NOT, WHY NOT?);

The written procedures are reviewed as part of the FDA inspection of licensed manufacturers. Inspectors examine the procedures for adequacy in terms of completeness, timeliness and follow-up action on all oral and written complaints received. Any significant deficiencies are brought to the attention of the responsible head of the establishment.

(c) WHAT SYSTEMS, TECHNIQUES, OR APPROACHES DOES FDA USE TO ASSURE THAT THE COMPANY'S PROCEDURES FOR RESPONDING TO COMPLAINTS AND ADVERSE REACTION REPORTS ARE FULLY IMPLEMENTED AS WRITTEN?

As indicated in accordance with Title 21 of the Code of Federal Regulations, section 211.198, the manufacturer must establish and follow written procedures describing the handling of all written and oral complaints regarding a drug product. A written record of each complaint is maintained in a file designated for drug product complaint. The file should include the following information, where known: the name and strength of the product; lot number; name of complainant; nature of complaint; and reply to complainant. When an investigation of the product records is conducted, the written record should include the findings of the investigation and follow-up. When an investigation of the production records is not conducted, the written record should include the reason that an investigation was found not to be necessary and the name of the responsible person making the determination. The manufacturers are inspected on a routine basis and the complaint files are required to be readily available for inspection. The inspector can observe the implementation of the manufacturer's written procedures for handling complaints.

(d) IS THE FDA AWARE OF ANY INFORMATION THAT THESE PROCEDURES ARE NOT BEING/OR HAVE NOT BEEN FOLLOWED IN ANY CASE? IF SO, PLEASE PROVIDE THAT INFORMATION?

An extensive search of the inspection files for each biologic product manufacturer would be necessary to determine whether or not firms were ever found to be deficient in a particular area of the regulations.

A search of the inspection files for the last 5 years (1978-present) for the three companies listed in question 6(a) failed to reveal any reported deficiencies in the manner in which they handle complaints.

(e) IS THE FDA CONSIDERING EITHER REVISING SECTION 211.198 TO REQUIRE MORE EXTENSIVE FOLLOW-UP BY MANUFACTURERS IN CASES INVOLVING REPORTS OF ANY OF THE REACTIONS LISTED IN QUESTION 1 (ABOVE) OR REQUIRING REVISION OF THE WRITTEN PROCEDURES WITHOUT ANY CHANGE IN THE REGULATIONS TO ASSURE MANUFACTURER TRACKING AND RECORDKEEPING OF SIGNIFICANT POST-REACTION SEQUELLAE?

At this time, FDA is not planning to revise section 211.198, nor are we considering requiring revisions without a change in the regulations.

7. IS THE HHS DEPARTMENT CONSIDERING ATTEMPTING TO DEFINE CATEGORIES OF POTENTIALLY HIGH RISK CHILDREN (I.E., POTENTIALLY AT HIGHER RISK OF SIGNIFICANT ADVERSE REACTION TO PERTUSSIS VACCINATION THAN CHILDREN IN THE NORMAL POPULATION) FOR THE PURPOSE OF PROVIDING ADDITIONAL INFORMATION AND GUIDANCE TO PHYSICIANS, STATE AND LOCAL HEALTH DEPARTMENTS, PUBLIC HEALTH CLINICS, ETC.?. . .

HHS is interested in identifying factors which might predict significant adverse reactions to pertussis vaccination. As indicated in Section 3 of the report to Senator Hawkins, we are currently reviewing policies and recommendations from other countries and consulting the medical literature with regard to current contra-indications. Individual reaction reports in HHS or manufacturer files have been considered in determining contraindications in the past; use of this source of information will be continued. The MSIFI system in particular is just now getting systematized. Such reports will be a part of further considerations. Followup of all reports of neurological events reported following vaccination will provide additional information about pre-existing conditions which is not present on the current report forms. We would be pleased to receive reports of reactions discovered in letters from parents and include these in the considerations. The Department's approach to arriving at definitions of contraindications and precautions is through consultation with a variety of groups, including but not limited to the Immunization Practices Advisory Committee (ACIP)and FDA's Vaccine Advisory Committee. Meetings of these committees are open to the public and announced in the Federal Register. The basis for the current recommendations of the Department of Health and Social Security, United Kingdom, and those of the ACIP and the AAP are under review by CDC. The results of this review are to be presented to the ACIP at its meeting on October 18-19, 1983.

9. IN DR. BRANDT"S LETTER TO REP. MICA (REFERRED TO ABOVE), THE FOLLOWING QUESTION AND ANSWER WAS INCLUDED:

"SHOULD PARENTS HAVE A CHOICE AS TO WHETHER TO GIVE THE [PERTUSSIS] SHOT?"

"WE URGE THAT HEALTH CARE PROVIDERS DISCUSS THE RISKS AND BENEFITS OF ALL VACCINATIONS WITH PARENTS."

(a) SPECIFICALLY, WHAT STEPS HAS HHS TAKEN TO "URGE" HEALTH CARE PROVIDERS TO DISCUSS RISKS AND BENEFITS OF PERTUSSIS VACCINATION WITH PARENTS? DOES THE DEPARTMENT HAVE ANY EMPIRICAL EVIDENCE, STUDIES, OR OTHER PROOF THAT THESE STEPS TO URGE DOCTOR-PARENT DISCUSSION OF RISKS AND BENEFITS PRIOR TO VACCINATION IS WORKING IN FACT, I.E., THAT HEALTH CARE PROVIDERS ARE ENGAGING IN DETAILED DISCUSSIONS OF VACCINE RISKS AND BENEFITS WITH PARENTS BEFORE CHILDHOOD IMMUNIZATIONS?

HHS sponsored a survey of public attitudes and practices towards immunizations in 1979. This indicated that, of families in which children had received DTP vaccination in the preceding 12 months, 43 percent had had information presented to them about risks and benefits and 33 percent had signed a form. This survey also indicated that 3 percent of children who had received DTP in the past year had a reaction that required a visit to a doctor, hospital, or clinic.

HHS through its publications and presentations, and recommendations of the ACIP, urges all health-care providers to discuss risks and benefits of all vaccinations with the recipients or their parents. The "General Recommendations on Immunization" of the ACIP state: "Parents and patients should be informed about the benefits and risks of vaccines. It is essential that the patient or the responsible person be given information concerning the risks of vaccines as well as the major benefits from vaccines in preventing disease in both individuals and the community. Benefit and risk information should be presented in terminology that is as simple as possible. No formal and legally acceptable statement has been universally adopted for the private medical sector. CDC has developed 'Important Information Statements' for use with federally purchased vaccines given in public health clinics. Practitioners may wish to consider these or similar materials for parents and patients. The Committee recommends that there be ample opportunity for questions before each immunization." Increased provider-parent dialogue regarding risks of disease, risks and benefits of vaccine, and the recognition and reporting of any adverse event are recommended for discussion during these question periods.

(d) WHAT PLANS, IF ANY, DOES HHS HAVE TO IMPROVE THE IMPORTANT INFORMATION FORM AND TO ASSURE ADEQUATE WRITTEN PARENT INFORMATION IS PROVIDED ON THE RISKS AND BENEFITS OF PERTUSSIS VACCINATION BY BOTH PRIVATE PRACTITIONERS AND PUBLIC CLINICS?

Important information forms for all childhood vaccines have been in use since 1977-1978. They were revised in 1979-1980 and have been in a further process of revision since October of 1982. Revised forms are now available and being distributed to State and local health departments. It is anticipated they will go into widespread use approximately by August 1, and into exclusive use by October 1, 1983. To assure that important information statements are being properly used, each grantee is required to address the issue of important information forms on a quarterly basis; and on each field visit to conduct reviews of immunization programs, the use of important information forms is specifically addressed. At this moment, there is no mechanism envisioned which could assure adequate information is provided in private practitioners' offices.

(e) WHAT PLANS, IF ANY, DOES HHS HAVE TO ASSURE ADEQUATE WRITTEN PARENT INFORMATION IS PROVIDED ON MONITORING OF CHILDREN RECEIVING PERTUSSIS VACCINE, ON CONTRAINDICATIONS AND HIGH RISK CONDITIONS, ON PREVENTIVE MEASURES PARENTS CAN TAKE TO MINIMIZE THE RISKS OF SERIOUS ADVERSE REACTIONS, ON PARENTS' RIGHT TO REPORT ADVERSE REACTIONS, ETC., BY BOTH PRIVATE PHYSICIANS AND PUBLIC CLINICS?

See response to item d. The Important Information forms specifically request that parents report adverse reactions to the local health departments. The portion of the Important Information form requesting this report contains a telephone number to receive the report and is given to the parent to take home.

(f) WOULD THE DEPARTMENT FAVOR LEGISLATION TO REQUIRE THAT WRITTEN RISK AND BENEFIT INFORMATION, AND INFORMATION OF THE TYPES REFERRED TO IN QUESTION 9(e) IS PROVIDED TO PARENTS BY PRIVATE OR PUBLIC HEALTH CARE PROVIDERS PRIOR TO PERTUSSIS VACCINATION?

We believe the current mechanism is adequate to assure use of the Important Information forms in the public sector. The Department also feels that legislation would not necessarily assure their use in the private sector.

10. PLEASE STATE WHETHER OR NOT HHS FAVORS OR OPPOSES STATE LAWS WHICH AUTHORIZE AN EXEMPTION FROM MANDATORY VACCINATION REQUIREMENTS BECAUSE OF "PHILOSOPHICAL OBJECTION" OR "PERSONAL CONVICTION"? WHY DOES THE DEPARTMENT TAKE THIS POSITION? DOES THE DPEARTMENT FAVOR OR OPPOSE A "RELIGIOUS OBJECTION" EXEMPTION FROM MANDATORY VACCINATION? WHY? IF THE "RELIGIOUS" AND "PHILOSOPHICAL/PERSONAL" OBJECTIONS ARE NOT EITHER BOTH SUPPORTED OR BOTH OPPOSED BY HHS, PLEASE EXPLAIN THE REASONS FOR TAKING A DIFFERENT POSITION ON THE ONE TYPE OF OBJECTION THAN ON THE OTHER.

HHS neither favors nor opposes philosophical objection nor personal conviction exemptions from mandatory vaccination requirements. The model school immunization law drafted by the Centers for Disease Control and distributed in February 1981 provided for religious and medical exemptions but not for personal or philosophical exemptions. Religious exemptions have been a traditional part of immunization requirements. However, courts in at least two States (Arkansas, Maryland) have struck down religious exemptions in recent years. An important reason for not vigorously supporting personal/philosophical exemptions has been a feeling that it is likely many parents would choose to claim such exemptions rather than go to the trouble of locating immunization records or (if their child needed them) obtaining needed immunizations.

11. PLEASE INDICATE ON A STATE-BY-STATE BASIS WHETHER THE INCIDENCE OF WHOOPING COUGH (REPORTED AND BACTERIOLOGICALLY CONFIRMED) INCREASED AFTER ADOPTION BY EACH STATE WHICH HAS DONE SO OF A "PERSONAL CONVICTION" OR "PHILOSOPHIC OBJECTION" EXEMPTION FROM MANDATORY PERTUSSIS VACCINATION? IF SO, BY WHAT PER CENT ON A PER CAPITA BASIS DID THE DISEASE INCREASE?

Data are not available which would permit analysis of incidence of pertussis before and after adoption of personal/philosophical exemptions from mandatory immunization. It should be noted that States which allow personal/philosophical exemptions do so generically, rather than for any specific immunization alone.

(a) IS THERE ANY SIGNIFICANT DIFFERENCE ON A PER CAPITA BASIS IN THE WHOOPING COUGH INCIDENCE RATE (REPORTED AND CONFIRMED) BETWEEN STATES WHICH PERMIT SUCH EXEMPTIONS AND STATES WHICH DO NOT?

There are six States which do not require pertussis immunization for school entrance (Arizona, Kentucky, Missouri, New York, Pennsylvania, Rhode Island). In 1982 the provisional pertussis incidence rate in those States was 1.394 cases per 100,000. Sixteen States which require pertussis vaccination allow personal or philosophical exemptions for immunizations (California, Colorado, Delaware, Idaho, Louisiana, Maine, Michigan, Minnesota, Montana, North Dakota, Ohio, Oklahoma, Utah, Vermont, Washington, Wisconsin). The provisional pertussis rate in those States in 1982 was 0.63 cases per 100,000. The remainder of States require pertussis immunization and do not permit personal/philosophical exemptions. The provisional pertussis rates in those States is 0.66. The difference in incidence rate between States which do not require pertussis at all and those which do is significant. There is no significant difference in the reported pertussis incidence rate in States which require pertussis immunization and allow personal/philosophical exemptions as compared with those which require pertussis immunization and do not allow such exemptions.

(b) ON A STATE-BY-STATE BASIS, HOW MANY EXEMPTIONS HAVE BEEN REQUESTED ON THE "PERSONAL CONVICTION" OR "PHILOSOPHIC OBJECTION" GROUNDS SINCE 1970?

Data are not available to permit a response to this question since this information is not systematically reported to CDC. However, data from the States which do report such information to CDC indicate that less than 1 percent of students have personal or philosophical exemptions.

(c) HAS THE ANNUAL NUMBER OF EXEMPTION REQUESTS INCREASED SINCE APRIL 1982? BY HOW MANY?

No data exist to answer this question.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
Atlanta, Georgia 30333

August 4, 1983

Mr. Jeffrey Schwartz
Dissatisfied Parents Together
Box 563, 1377 K Street, NW
Washington, D.C. 20005

Dear Mr. Schwartz:

Enclosed are answers from FDA to questions 8, 9 and 12 contained in your letter of April 29. This, along with our answers of July 20, completes our response.

Sincerely yours,

Walter R. Dowdle, Ph.D.
Director, Center for Infectious Diseases
and
Chairman, Interagency Group to Monitor
Vaccine Development, Production and Usage

Enclosure

8. IN DR. BRANDT'S LETTER TO REPRESENTATIVE MICA (REFERRED TO ABOVE), THE FOLLOWING QUESTION AND ANSWER WAS INCLUDED:

> "20. DO YOU THINK THAT REACTIONS TO PERTUSSIS VACCINE SHOULD BE A MANDATORY REPORTING ELEMENT FOR DOCTORS?"

"WE BELIEVE THAT SEVERE OR UNEXPECTED REACTIONS TO ANY VACCINE SHOULD BE REPORTED BY PHYSICIANS. IT IS UNLIKELY THAT EVEN IF MANDATED, THIS COULD SATISFACTORILY BE IMPLEMENTED."

(a) DOES FDA/HHS/CDC HAVE THE AUTHORITY EITHER DIRECTLY OR INDIRECTLY UNDER EXISTING LEGISLATION TO MANDATE SUCH REPORTING BY PRIVATE PHYSICIANS? IF NOT, WOULD FDA/HHS FAVOR LEGISLATION TO CONFER UPON IT SUCH AUTHORITY OR TO DIRECTLY REQUIRE SUCH REPORTING? (IF NOT, WHY NOT?)

The types of recordkeeping and adverse reaction reporting requirements that you have inquired about are the type of requirements that would normally be imposed under the current good manufacturing practices (CGMP's) provisions of the Federal Food, Drug, and Cosmetic Act ("FDC Act"). Biological products are drugs and as such are required to be manufactured in accordance with CGMP's. However, the CGMP requirements do not apply to the practice of medicine. We can and do impose these types of recordkeeping requirements on manufacturers, processors, and packers of drug products, but do not have authority to impose similar requirements on physicians. Nor would it appear that other provisions of the FDC Act or the Public Health Service Act would provide such authority.

In regard to the second part of your question, FDA/HHS believes that requiring mandatory reporting of adverse reactions by physicians would be a significant additional burden, would be difficult to enforce, and thus would be regarded as controversial. In view of the current efforts to address the problem of adverse reaction reporting alluded to elsewhere in our response, we believe that it would be premature to foster such legislation without further careful deliberation and discussion of the matter with outside advisory groups. It should also be noted that such a requirement would likely incur significant costs for providing for the review of this additional information and for enforcement.

Most current reporting systems concerned with the occurrence of diseases or of adverse reactions are voluntary. Under these systems, underreporting is a common feature. Nonetheless, such systems provide useful data concerning trends in frequency of the observed events which are of epidemiologic value even in the absence of the reporting which is 100% complete.

(b) DOES FDA/HHS/CDC HAVE THE AUTHORITY UNDER EXISTING LAW TO REQUIRE THE MANUFACTURER OF A LICENSED PERTUSSIS VACCINE TO INCLUDE AS AN EXPRESS CONDITION OF ITS CONTRACT OF SALE TO ANY PURCHASER OF THE VACCINE THAT THE PURCHASER SHALL REPORT ALL SEVERE REACTIONS OF WHICH IT BECOMES AWARE TO THE CDC AND SHALL REQUIRE IDENTICAL PROVISIONS TO BE EXPRESSLY INCLUDED AS A CONDITION OF ALL SUBSEQUENT SALES OF THE

VACCINE? IF SO, IS FDA CONSIDERING IMPLEMENTING THIS AUTHORITY? (IF NOT, WHY NOT?) IF FDA/HHS/CDC DOES NOT HAVE THE ABOVE AUTHORITY UNDER EXISTING LAW, WOULD FDA/HHS/CDC FAVOR LEGISLATION TO CONFER UPON IT SUCH AUTHORITY?

As noted above, FDA does not have authority to directly require physicians to report adverse reactions. It is therefore doubtful that FDA could do indirectly, i.e., by requiring manufacturers to contractually impose reporting requirements upon physicians, what it cannot do directly. Moreover, even if FDA could require such a contractual provision, enforcement of the provision would be very difficult. FDA could not inspect physicians' offices, nor could FDA take any action against a physician who failed to make such reports. As discussed above, FDA believes that a voluntary physician-adverse reaction reporting system is appropriate.

(c) HOW SHOULD "SEVERE OR UNEXPECTED" REACTIONS BE DEFINED FOR REPORTING PURPOSES ONLY?

Severe or unexpected reactions could be defined to include an event which is either:

1. not reported in the direction circular;

2. potentially life-threatening/fatal;

3. permanently disabling;

4. requires hospitalization for treatment;

5. requires extensive therapy for treatment; and/or

6. takes longer than 15 days for recovery.

(d) SAME QUESTIONS AS (a) AND (b) ONLY WITH RESPECT TO THE AUTHORITY TO REQUIRE DIRECTLY OR INDIRECTLY WRITTEN RECORDKEEPING BY THE ADMINISTERING PERSON OF THE MANUFACTURER'S NAME AND LOT NUMBER OF DATE OF ADMINISTRATION FOR EACH VACCINATION CONTAINING PERTUSSIS?

FDA probably could not require manufacturers to make physicians keep records.

(e) WOULD HHS/FDA/CDC FAVOR GIVING DIRECT INFORMATION TO PARENTS ON THEIR RIGHT TO FILE ADVERSE REACTION REPORTS DIRECTLY WITH CDC? WOULD HHS/FDA/CDC FAVOR REQUIRING PHYSICIANS TO NOTIFY PARENTS OF THIS RIGHT IN WRITING. WHY OR WHY NOT?

Parents of children given DTP, measles-mumps-rubella and poliovirus vaccines in public programs already receive an "information form which solicits reports of reactions occurring within four weeks of immunization to a responsible individual." This information regarding significant reactions is then relayed to CDC. The American Academy of Pediatrics Committee on Infectious Diseases (the "Redbook" Committee) has reprinted these forms in their latest Report

(1982) and has indicated that, "...practitioners should consider the use of these or similar materials for parents and patients...." The physician may report reactions to either the manufacturer, the USP, or to FDA directly.

Although encouraging physicians to notify parents of their right to report adverse reactions might result in more reported adverse reactions, FDA does not have authority to require that they distribute the information.

(f) WHAT IS HHS/FDA/CDC DOING AND PLANNING TO DO TO ENCOURAGE PRIVATE PHYSICIAN REPORTING OF SEVERE ADVERSE REACTIONS?

The FDA encourages private physicians to report severe adverse reactions as follows:

i. A Drug Experience Report Form (FDA 1639) is provided to approximately one and one-half million health professionals with the FDA Bulletin.

ii. The FDA sponsors an exhibit featuring adverse reaction reporting at various health professional meetings. Individuals are encouraged to report reactions and the procedures for submitting reports are explained.

iii. The majority of reports from individuals are acknowledged by FDA in the form of a phone call or letter. Reporters are thanked for submitting the report and are encouraged to report further reactions.

iv. The Drug Experience Report Form is provided in tear-out form in the AMA Drug Evaluations, published by the American Medical Association in 1983. Physicians are encouraged to report reactions in the section on adverse reactions. This form is also included periodically in the "FDA Drug Bulletin".

9. IN DR. BRANDT'S LETTER TO REPRESENTATIVE MICA (REFERRED TO ABOVE) THE FOLLOWING QUESTION AND ANSWER WAS INCLUDED:

"SHOULD PARENTS HAVE A CHOICE AS TO WHETHER TO GIVE THE (PERTUSSIS) SHOT?"

"WE URGE THAT HEALTH CARE PROVIDERS DISCUSS THE RISKS AND BENEFITS OF ALL VACCINATIONS WITH PARENTS."

(b) SHOULD VACCINE MANUFACTURERS BE REQUIRED TO PROVIDE WRITTEN RISK AND BENEFIT INFORMATION DIRECTLY TO PARENTS PRIOR TO VACCINATION? WHY OR WHY NOT? DOES THE DEPARTMENT HAVE THE LEGAL AUTHORITY UNDER EXISTING LAW TO PRESCRIBE AND ENFORCE SUCH A REQUIREMENT?

Biological products, such as vaccines, are drugs and are subject to the labeling requirements of the Federal Food, Drug, and Cosmetic Act (FDA Act). Section 502 (a) of the FDC Act prohibits false or misleading labeling. FDA has determined that, without a patient package insert, the labels of certain prescription drugs are misleading because they fail to reveal facts about the consequences that may result from the use of the drugs. This position was upheld in Pharmaceutical Manufacturers Ass'n v. FDA, 634 F. 2d 106 (3rd Cir., 1980). Although FDA could require manufacturers to provide to physicians a patient package insert with each dose of vaccine, FDA could not compel physicians to provide this information to their patients. The information provided to a patient about the risks and benefits of a drug is considered to be the practice of medicine and is not an area that FDA regulates.

(c) SHOULD PERTUSSIS VACCINE MANUFACTURERS BE REQUIRED TO INCLUDE IN ITS SALE CONTRACT A PROVISION SUCH AS THAT STATED IN QUESTION 8(b), EXCEPT WITH RESPECT TO THE PROVISION TO EACH PURCHASER OF THE VACCINE (INCLUDING THE ULTIMATE USER--THE PARENT OF THE VACCINEE) OF ADEQUATE WRITTEN INFORMATION ON THE BENEFITS AND RISKS OF THE VACCINE? WHY OR WHY NOT? DOES FDA/HHS HAVE THE AUTHORITY UNDER EXISTING LAW TO IMPOSE SUCH A REQUIREMENT AS A CONDITION OF LICENSURE OR OTHERWISE?

See answer to question 8(b). Although FDA does not have authority to mandate such a requirement, the committee believes that benefit and risk information should be presented to patients and parents. See answer to question 9(a).

12. IN DR. BRANDT'S ANSWER TO REPRSENTATIVE MICA's QUESTION #4, IT IS STATED THAT "LICENSURE [OF THE JAPANESES ACELLULAR PERTUSSIS VACCINE] FOR WIDE-SCALE USE [IN THE UNITED STATES] WILL TAKE SEVERAL YEARS."

(a) WHY IS THIS SO? SPECIFICALLY, WHAT STEPS HAVE TO BE TAKEN (AND WHAT SPECIFIC CRITERIA MET) FOR THIS NEW VACCINE TO QUALIFY FOR LICENSURE?

The requirements for filing and obtaining approval to market a new vaccine in this country are the same for all manufacturers. Each manufacturer is required to file an establishment license application describing the facilities used to manufacture the vaccine and a product license describing the method of production as well as the tests and data to demonstrate the safety, purity, potency and effectiveness of the product. In addition, each manufacturer must develop standardized laboratory tests in order to assure batch-to-batch consistency and to provide a basis for establishing the dating period for the product.

(b) HOW LONG APPROXIMATELY SHOULD EACH STEP TAKE?

It should be noted that as of this response, no license application for a Japanese or Japanese-type pertussis vaccine has been received by the Office of Biologics. Until an application has been received and reviewed, it is very difficult to predict with any accuracy the time required for licensing. However, as an example, the development and initiation of a clinical field trial followed by the review and analysis of the data collected may take two to three years depending upon the availability of a suitable population to conduct the trials and the criteria (protocol) for establishing the safety and efficacy parameters.

(c) ARE THESE REQUIREMENTS AND CRITERIA MORE STRINGENT THAN THE LICENSURE REQUIREMENTS AND CRITERIA WHICH HAVE BEEN APPLIED TO THE WHOLE CELL PERTUSSIS VACCINES NOW IN USE IN THE UNITED

STATES? IF SO, IN WHAT RESPECTS? ARE THESE REQUIIREMENTS AND CRITERIA MORE STRINGENT THAN THOSE APPLIED TO ELI LILLY'S TRISOLOGEN PRODUCT? IF SO, IN WHAT RESPECTS?

Since the initial licensure of some of the whole cell pertussis vaccines was over thirty years ago, it is reasonable to expect that the requirements and criteria for licensure are more stringent today for any new vaccine intended to be introduced for marketing in the United States. Today we would require substantial evidence of the safety and effectiveness of the vaccine, additional laboratory testing to characterize the vaccine, and greater manufacturing controls over the production of the vaccine. Since Lilly's Trisologen/TM was approved for marketing in the 1960's, today's requirements and criteria would be more stringent as explained above.

(d) IN THE DEPARTMENT'S VIEW IS IT IN THE PUBLIC INTEREST TO APPLY MORE STRINGENT STANDARDS AND TESTS FOR LICENSURE OF NEW VACCINES THAT HAVE SHOWN THEY CAN MEET STANDARDS AND TESTS WHICH APPLIED AT THE TIME OF LICENSURE (AND LICENSE REVIEW) OF CURRENT VACCINES, IF SUCH TESTS SHOW THE NEW VACCINES TO BE SUBSTANTIALLY LESS REACTOGENIC/NEUROTOXIC THAN THE CURRENTLY LICENSED VACCINES?

Many of the standards and tests which would apply to a new pertussis vaccine are already established in the Code of Federal Regulations (CFR). The decision on whether or not to license a new pertussis vaccine depends not only on its degree of reactogenicity and neurotoxicity, but on other key factors such as its efficacy. A new vaccine submitted for licensure might well demonstrate a very low level of reactogenicity, for example, but fail to be efficacious. We would therfore expect a new pertussis vaccine, as a minimum, to meet the current standards for safety, purity, potency, and efficacy. If, nowever, data were developed to show that the safety and efficacy standards already established in the CFR were not appropriate for a particular new vaccine, FDA would establish a standard for that vaccine.

(e) WHAT INFORMATION DOES THE DEPARTMENT HAVE (OR KNOW OF) CONCERNING THE (i) POTENCY OF THE JAPANESE ACELLULAR VACCINE; (ii) THE ABILITY OF THE JAPANESE ACELLULAR VACCINE TO PASS THE MOUSE WEIGHT GAIN TEST; (iii) THE REACTOGENICITY/NEUROTOXICITY OF THE JAPENESE ACELLULAR VACCINE, AS MEASURED BY APPLICABLE JAPANESE TESTS: (iv) THE CLINICAL EXPERIENCE IN JAPAN (OR ELSEWHERE) WITH THE VACCINE'S POTENCY AND REACTOGENICITY/NEUROTOXICITY? PLEASE PROVIDE AS MUCH OF THIS INFORMATION AS IS CURRENTLY AVAILABLE?

FDA obtained samples of the Japanese acellular pertussis vaccine from the Japanese National Institute of Health (NIH) pursuant to an agreement that FDA would not release any information concerning the vaccine without the consent of the Japanese government. FDA has conducted laboratory tests on these vaccines, but considers this information confidential because of the agreement with the Japanese government.

To our knowledge, the Japanese vaccine has not been used outside of Japan. Preliminary clinical results with the acellular vaccine in Japan were reported by Professor Kimura in the workshop on "New Pertussis Vaccines-- Laboratory and Clinical Evaluation." No published clinical results detailing the clinical safety, potency, and/or evidence of clinical efficacy of the acellular vaccine pertussis vaccine are available.

(f) WHAT STEPS, IF ANY, IS THE DEPARTMENT PLANNING TO TAKE TO EXPEDITE, OR ENCOURAGE EXPEDITION OF, TESTING AND LICENSURE OF THE JAPANESE ACELLUALR VACCINE? WHEN DOES THE DEPARTMENT PLAN TO TAKE THESE STEPS?

The ultimate decision of whether or not to submit a new pertussis vaccine to FDA for licensure rests with the manufacturers. However, FDA has indicated its interest in the evaluation of the current Japanese vaccine or a Japanese-like vaccine. Discussions have been held with each of the three major manufacturers to encourage them to pursue an acellular pertussis vaccine. In addition, FDA has been in contact with the Japan National Institute of Health (NIH) regarding samples of the Japanese vaccine for both clinical and laboratory testing. Because of liability concerns, the Japanese have restricted our use of any samples which they might supply to us for laboratory evaluation only. Each of the U.S. commercial manufacturers of pertussis vaccine has stated that they have ongoing efforts to develop an improved vaccine. In anticipation of the submission of a Japanese-like acellular vaccine for licensure, as noted above, FDA has done some laboratory tests with samples supplied by the Japan NIH. As a followup, the Japanese have sent FDA 300 mL samples from each of five additional lots of pertussis vaccine for laboratory testing; these tests are in progress. FDA is prepared to conduct laboratory testing of experimental lots of new pertussis vaccine candidates as soon as they are developed.

Senator HAWKINS. Mrs. Gary, have you considered litigation?

Mrs. GARY. No, that has never been a consideration in our family. We really felt that it was more important to—nothing is going to bring that baby back. I don't think the doctor was malicious in giving the routine shot. I am sorry that he apparently was so ill-informed, but we really want to do something with our energy to change this condition going on as it is.

If I may just refer to what you were asking of Jeff as far as the Government compensation, the one thing I would be concerned about personally in that—and since we are not in any kind of litigation, maybe I can say it rather objectively—how would the manufacturers of vaccine and how would the doctors be held accountable if the Government were financially supporting those vaccine-injured children? I just would be afraid that perhaps the situation would continue without the accountability. How would that be built into the bill?

Senator HAWKINS. What was the cause of death listed on the death certificate of your granddaughter?

Mrs. GARY. SIDS. Sudden infant death syndrome.

I have since talked with a doctor who went over the autopsy report, and he feels that it should be listed as atypical SIDS and to make sure that it is listed on there that the DPT inoculation was within 4 hours, because that is not on there. It is just SIDS.

Senator HAWKINS. Are they going to add the other?

Mrs. GARY. I haven't learned how to do that yet. I don't know to do that, and I am in the process of learning how that has to be done.

Senator HAWKINS. We will be glad to work with you.

Do you have any other grandchildren?

Mrs. GARY. Yes, we had one that was born just 5 weeks before Lee Ann, and we have had one in January of this year.

Senator HAWKINS. Have any of them been vaccinated since your other granddaughter's death?

Mrs. GARY. Our first one has had his three shots. His mother is now very much concerned that the time is approaching for his fourth. She really is hesitating about having that, having learned through my research that just because you have gotten through each shot doesn't necessarily mean that there won't be damage on subsequent ones.

My youngest daughter's baby was born in January. She adamantly refuses. I forgot to include that she also mentioned at the time the baby died—she happened to be visiting with us; she lives in California. She absolutely shrieked, "It's just like Rhonda's baby. I know it was that shot." Everybody was in agreement except the doctors don't think there is any connection to it, except for some doctors.

Senator HAWKINS. I believe you said in your testimony that you are working with someone to form a Massachusetts DPT group.

Mrs. GARY. Yes, I have just recently been in contact with one woman because I have been concerned about those numbers who don't know; they have this child and they just don't know that there could be a relationship.

I had an opportunity to talk on the phone with this one woman who has the 4-year-old, and I was the first person who had called her that had any awareness outside of her having seen the Phil Donahue program and having talked to a lawyer who is a mutual acquaintance of ours. My heart went out to that young woman because she was living with this situation for 4 years. When she would even mention her own suspicions, people raised their eyebrows at her.

I think there are a lot of people out there, and I want to find them in our State to see what kind of help we can be in a mutual support system.

Senator HAWKINS. We laud your efforts. You have been very helpful.

Mr. SCHWARTZ. Senator Hawkins, if I may, I would just say that we have been spontaneously contacted by parents all over the country who have said, "How do we set up local State chapters of DPT?" Our group hasn't gone out soliciting. They have flooded into us. So we are offering to coordinate and help put people in touch with each other to assist, as Donna Gary has done on her own in Massachusetts. If people want to start or join State chapters of Dissatisfied Parents Together [DPT] they can write us at DPT, Box 563, 1377 K Street NW., Washington, DC 20005, or they can call us at our answering service—(202) 543-4211. We will help them form or join State chapters.

Senator HAWKINS. We appreciate that.

Mr. Kudabeck, I know you are opposed to the legislation. It is my understanding that originally the State you lived in allowed a philosophical exemption from the shot, and then you moved to Arkansas where they mandate it?

Mr. **Kudabeck**. In Illinois our children were allowed exemptions based on our personal beliefs. In some areas, however, there is still a bit of a problem.

Senator **Hawkins**. Where?

Mr. **Kudabeck**. In some schools you can go in and sign that you will take your children out of school for a couple of weeks if there is an epidemic and in other schools they are adamant. It often depends on how high the immunization rate is in the school. If it is 80 percent or better, the parents have usually had no problems with it in the past.

Senator **Hawkins**. This is in Arkansas?

Mr. **Kudabeck**. No, that is in Illinois.

Senator **Hawkins**. Illinois?

Mr. **Kudabeck**. Right.

Senator **Hawkins**. What about Arkansas?

Mr. **Kudabeck**. Arkansas is strictly a police state.

Senator **Hawkins**. It is a police state?

Mr. **Kudabeck**. Strictly.

Might I add, not to interrupt your question, but on the important information forms, on the back it talks about reactions. It says, "If the person who received the vaccine gets sick and visits a doctor, hospital, or clinic in the 4 weeks after the vaccination, please report it to"—and it is left blank.

Senator **Hawkins**. It does not say whom to report it to?

Mr. **Kudabeck**. No, it doesn't do that. They are supposed to have a rubberstamp.

Then a little below that it says—and they went to a small card on this—"I have read the information on this form about polio and the oral vaccine. I have had a chance to ask questions which were answered to my satisfaction." I might add here that most parents, we have found, do not know what questions to ask and feel that to do so would be an exercise in futility since there is no choice anyway. From our own personal experience, we have found those administering vaccines to be provaccine and minimize the risks. Direct answers to questions are often very difficult to obtain. The form then states, "I believe I understand the benefits"—not "I understand," but I believe I understand the benefits—"and risks of oral polio vaccine and request that it be given to me or to the person named below, for whom I am authorized to make this request."

Which one of my children should I offer first as an experiment to find out if they may be damaged? There isn't enough money in the Treasury of the United States that would replace any one of my children or any part of them.

Senator **Hawkins**. Do you agree that we need to mandate the Federal Government conduct more tests on adverse reactions?

Mr. **Kudabeck**. It would be a good idea.

I think that the problem, Senator, is the fact that compensation without the right, without the basic, inalienable right, to say no to that shot, will only preclude problems in the courts such as in Arkansas where their State epidemiologist said that he could hardly wait until a compensation bill was passed because it would eliminate a lot of his problems.

There is a mother, Joanne Cook, who had five doctors who said, "No, you should not give your child another immunization. Don't do it because there could be damage." He will not accept that. He said if they don't do it, just bring him over to the health department and "We'll give him a shot."

Senator HAWKINS. Would you agree that the body determining compensation should be separate from the Federal Government?

Mr. KUDABECK. Well, if they took away the mandatory vaccination itself, then I think that the problem would not be there. I think that the normal tort system would be sufficient.

Senator HAWKINS. Should parents have the right to choose to pursue their case through the tort system?

Mr. KUDABECK. Yes. I think they should, yes.

Senator HAWKINS. Would you support making this administrative remedy exclusive; that is, removing the parents' right to sue for damages through the courts, which is preventing a lot of Senators from cosponsoring this bill?

Mr. KUDABECK. I don't believe I understand.

Senator HAWKINS. A lot of Senators want an exclusive remedy. If you are going to get compensation through the injury table, they want to eliminate your right to choose a tort recovery.

Mr. KUDABECK. The tort system altogether?

Senator HAWKINS. Eliminate the tort system altogether.

Mr. KUDABECK. I don't think that would be a very good idea.

Senator HAWKINS. You understand a lot of these are lawyers?

Mr. KUDABECK. Yes.

Senator HAWKINS. Would you oppose establishment of an administrative remedy?

Mr. KUDABECK. At law?

Senator HAWKINS. Administrative body.

Mr. KUDABECK. If that were the case, Senator Hawkins, again we go back to the basic human right of saying "no." If you can't—in the OTA statement it says, "What is a more serious weakness in the Government's defense strategy is the contention that a properly warned vaccine recipient has assumed all risk of injury."

We are coerced into signing these forms saying we request it, and then we have no option to say no. What difference does it make which way you are going to seek a remedy? I am being forced—I have been in the court for the past 8 months. I go again for a trial jury. I was found guilty of truancy because I enrolled my children in school; I did not take them out; they suspended them; they kicked them out and charged me with truancy. We enrolled them in another school. I asked the school principal at court, if I brought them back to school today, would he enroll them. He said, "No." The judge, without deliberation, found me guilty, and charged me a $750 fine. He said, "If you want a trial by jury, you have to go through this method." I asked for a trial by jury in the beginning and was refused that.

I stood on my constitutional rights. He said, "If you maintain your stature before me demanding those constitutional rights, you'll be in contempt of court."

Senator HAWKINS. Do you have a lawyer?

Mr. KUDABECK. Myself.

Senator HAWKINS. Yourself.

Do you know how many States have exemptions for religious or philosophical objections? Have you made that a study?

Mr. KUDABECK. If I remember correctly, it is 22 States. It is either 21 or 22; I am not sure exactly. Some of them are written loosely, and some are very tight.

Senator HAWKINS. Thank you so much.

Thank you so much for your participation here. I have a hard time questioning you because I am on your side.

Mr. KUDABECK. Thank you, Senator Hawkins.

Senator HAWKINS. Our next panel of witnesses, the third panel, is a professional panel which is composed of Dr. Martin Smith, Dr. Stephen King, Dr. Jonas Salk, Mr. Andrew Dodd, and Dr. Alan Nelson.

I would like to state, while we are changing the name signs for you, that Senator Hatch and Senator Kennedy have a conflict. They are in a Judiciary Committee hearing at this time, but they will read the record. They have expressed their interest in our holding this hearing.

I am interested in all the testimony given today, but I hope to have an opportunity to question all the witnesses. Therefore, we will submit your entire statement for the record, and we would like a summary not over 5 minutes, please, so that we can expedite the questioning of all the witnesses.

Dr. Smith, since you so ably represented the American Academy of Pediatrics in developing this legislation, we will give you the edge and let you start off.

STATEMENT OF MARTIN H. SMITH, M.D., PRESIDENT-ELECT, AMERICAN ACADEMY OF PEDIATRICS

Dr. SMITH. Thank you, Madam Chairman.

I am Dr. Martin H. Smith, representing the American Academy of Pediatrics, an organization of 27,000 board-certified pediatricians.

I am here to speak in strong advocacy of the National Childhood Vaccine Injury Compensation Act. In dealing with this particular issue, it would be well to remind the committee that the American Academy of Pediatrics has a 54-year history of existence primarily as an advocate for children, not solely for our membership. Our approach to this problem is in conformity with our purpose of advocating for children.

We feel that this is unique legislation. Compensation legislation is not a new consideration for the Congress, but compensation legislation in this instance is unique. We are dealing with a product that is required by law for the public good in all States before entry into school or, in some instances, before entry into any childhood situation at any age.

For over 7 years the academy has advocated as simple justice for children that if injury occurs, as is inevitable in a very small percentage of cases, the public owes to the victim a simple, direct, and prompt compensation, rather than an uncertain pursuit of justice through the prolonged and uncertain tort process.

In support of this philosophic approach it is appropriate to quote here from a 1981 verdict handed down by Judge Finesilver, a Federal district judge in Colorado. He was dealing with the settlement of a vaccine injury case when he said:

> So long as immunization plays a key role in our national health policy, unavoidable adverse reactions to vaccines will remain. Only an adequate no-fault compensation system can provide the necessary incentives to drug manufacturers, State and local health facilities, and critically, the American public, to continue to actively participate in emergency immunization programs.

Further on he said:

> National legislation is necessary to achieve this objective lest a patchwork approach be taken by the individual States in their salutary efforts in providing essential immunization programs.

This country has never enjoyed such freedom from preventable childhood diseases as is true at the present moment. Of all medical procedures, the full utilization of a complete immunization program is the easiest to document as to cost effectiveness. Yet, I must warn that we could be at a crisis point at any time, with either loss of supply of vaccine or such escalation of cost that it could result in a shattering of our present excellent program.

Other than providing a better form of justice for children, these concerns for supply and cost of vaccine, and the ability to continue a full immunization program, have been the greatest reasons for the tremendous interest of the academy in this subject.

With the doses administered each year of these products, there will be approximately two cases of paralytic polio or polio-like instances and at least 50 permanent neurological injuries that result. These occur without fault being involved in the part of the provider or the producer of the vaccine. This is the annual, year-in, year-out toll that is inevitable in maintaining an immunized population.

When serious injuries occur from any one of the vaccines, the emotional and financial toll for the families involved is severe. The financial stress begins immediately and it is difficult for any family to manage these costs. These costs are continual and often will extend over the lifetime of the victim. If a financial settlement is reached under the tort process, it is usually 6 to 8 years after these costs have begun compounding. From the beginning, the interest of the Academy of Pediatrics in this legislation has been to try to bring about real justice that is prompt and equitable for those children and their families who are the innocent victims of this difficult situation.

At the present time there is no avenue for compensation for vaccine injuries that can be sought except in the tort process. In some instances these have resulted in huge windfall settlements, while in other instances the victim may be unable to cope with the tedious tort process and no settlement is reached. In some instances there has been injury and significant expense, but there may not be enough prospect for a large enough settlement to justify the great deal of work needed by a thorough lawyer to bring action.

Nevertheless, the constantly increasing burden of large vaccine injury settlements has had a number of serious adverse effects on vaccine supply. The number of vaccine producers has been sharply reduced in recent years and the cost of vaccine has increased dramatically. Both of these effects have to be related to the burden of liability the vaccine producers are carrying at the present time. The result is that we now have only one source of supply for polio, measles, German measles, and mumps vaccine and only two, for practical purposes, sources of supply for DPT vaccine. This is certainly not a competitive situation which should be typical of the American way, and it is not a comfortable, secure supply situation.

We know that a real concern of the Congress will be the cost of a compensation program. We have seen the estimate of the Congressional Budget Office. We have not seen the details of their calculations, but we believe that the program can be put in place for much less than the Congressional Budget Office estimates. The Academy has commissioned an estimate by a respected Washington cost accounting firm, whose estimates are about one-fourth the estimate of the Congressional Budget Office. Even these estimates are probably high.

Our report calls attention to the fact that their estimates are based on the total cost of the program on the assumption that 100 percent of the claimants will opt for pursuit in the compensation system. While this may be the best method for calculating an estimate, it is certainly not the realistic appraisal of what may happen in an optional system.

The report calls attention to the fact that there is a considerable real cost in operation at the present time that we have not been able to calculate. The present liability cost under the tort process is incorporated into the present-day cost of the vaccines. That cost involved in the vaccines could be reduced in proportion to the acceptance of a compensation system.

A small indication of that cost is in the fact that the budget for the Government's immunization program had to be increased $7 million for the next year simply to do the same job in immunization that is given in the public sector alone. There are other costs that are hidden in the medicaid program, crippled children's program, and other Government programs in providing care for disabled children.

Let me again emphasize that the costs that are provided in this report are for total cost and not all of these costs are new costs.

While this could be looked upon as simple compensation legislation to take care of another instance of product liability, let me again stress that the justification lies in the fact that this is the only product, to my knowledge, whose use is required by law. This is a unique situation that is deserving of special remedies.

We are asking the Congress to assume a new responsibility in providing a system for compensation in these special instances, but it is not an untested idea. I call your attention to the fact that variations on this idea have functioned for several years in most of the western European nations and in Japan. Many of these nations are less capable of extending these benefits to their citizens than is this great country.

We have spent many hours debating some of the features that have gone into the writing of this legislation. It would be well to mention here some of the features that require particular consideration and give some explanation for them.

First, the legislation provides for an optional system. It certainly could be argued that a mandatory system could be more easily administered and the cost estimates could be developed more precisely. However, we have a great concern that the enactment of such a mandatory system would hold up under the test of constitutionality. It would be certain that it would be argued that a mandatory system deprives some individuals of their access to court.

Second, the legislation requires a prompt settlement of claims. This is fundamental to any improved system that is devised.

Third, the law mandates an obligation to pursue improved vaccines. This obligation now arises only through competition in the marketplace, when there is competition.

Fourth, the legislation requires the reporting of reactions rather than the present voluntary reporting. It is hoped that mandatory reporting will develop more exact data of the actual occurrence of reactions.

Fifth, the legislation makes provision for realistic awards. It is expected that with the awards being realistic, and with the system giving prompt settlements, there will be an incentive to accept the option of going into this system for settlement.

This should create a more even form of justice as opposed to the chances in the court of finding a possible involved settlement.

The academy appreciates this opportunity to present to this committee and to the Congress our interests and our concerns on the entire question of vaccine injury. We recognize that the problems involved here are not simple and that the answers, likewise, cannot be simple and direct answers. Yet, we are convinced that Congress can provide an answer for most of these problems. We would like to work with the Congress in doing that. We are convinced that the time is at hand when we must reach a direct and equitable resolution of a problem that has been building for a number of years. The problem is real. The costs of a resolution are not exorbitant. The cost of continued neglect can be much greater.

Thank you, and I will be glad to answer any questions.

[The prepared statement of Dr. Smith follows:]

American Academy of Pediatrics

TESTIMONY

BEFORE THE

UNITED STATES SENATE

COMMITTEE ON LABOR AND HUMAN RESOURCES

ON THE

NATIONAL CHILDHOOD VACCINE INJURY COMPENSATION ACT
S. 2117

PRESENTED BY

MARTIN H. SMITH, M.D., F.A.A.P.

MAY 3, 1984

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Mr. Chairman, I am Dr. Martin H. Smith, a pediatrician in private practice from Gainesville, Georgia and president-elect of the American Academy of Pediatrics. I am here to speak in strong support of "The National Childhood Vaccine Injury Compensation Act." In dealing with this particular issue, it would be well to remind the committee that the American Academy of Pediatrics has a fifty-four (54) year history of existence primarily as an advocate for children and our approach to this problem is consistent with that purpose.

We feel that this is unique legislation. Compensation legislation is not a new consideration for the Congress, but compensation legislation in this instance is unique. We are dealing with a product that is required by law for the public good in all states before entry into school or, in some instances, before entry into any childhood group situation at any age. For over seven years the Academy has advocated as simple justice for children that when an injury occurs, as is inevitable in a very small percentage of cases, the public owes to the victim a simple, direct, and prompt compensation, rather than the uncertain pursuit of justice through the prolonged and uncertain tort process.

In support of this philosophic approach, it is appropriate to quote from a 1981 verdict handed down by Judge Sherman G. Finesilver, a federal district judge in Colorado. In dealing with the settlement of a vaccine injury case, he stated:

> "So long as immunization plays a key role in our national health policy, unavoidable adverse reactions to vaccines will remain. Only an adequate no-fault compensation system can provide the necessary incentives to drug manufacturers, state and local health facilities, and critically, the American public, to continue to actively participate in emergency immunization programs. Preventive public health programs are of vital importance to the nation's population. Immunization programs are less expensive in terms of money and illness than the unnecessary toll of human lives and well-being brought about by the lack of such programs. However, persons who incur illness directly related to the immunization itself are entitled to recover compensation without the need to establish liability based on an illusive tort theory.
>
> "This field of national immunology cries out for a more expeditious and fairer way of determining legitimate claims and compensating victims of the vaccination. National legislation is necessary to achieve this objective lest a patchwork approach be taken by the individual states in their salutatory efforts in providing essential immunization programs." (Civil Action No. 78-F-452.)

This country has never enjoyed such freedom from preventable childhood diseases. Of all medical procedures, the full utilization of a complete immunization program is the easiest to document on a cost-effectiveness basis. Yet, I must express grave concern that we could be at a crisis point at any time, with either loss of supply of vaccine or such an escalation in cost that it could result in a shattering of our excellent program. Outside of developing a compensation program for children, our concerns for supply and cost of vaccine and the ability to continue a full immunization program have been the major reasons for the tremendous interest of the Academy in this subject.

Every year approximately 3,000,000 children are born in this country. For their basic immunizing, those 3,000,000 will each require three doses of DPT and two doses of oral polio vaccine. At eighteen months they require a booster dose of each of these vaccines and again, at school entry, a booster dose of DPT and oral polio. This results in a minimum of 15,000,000 doses of DPT and 8,000,000 doses of polio that are given each year. Even with proper administration and use of the best vaccine products available today, we can expect a case of polio-like disease to result out of each 5,000,000 doses of polio vaccine and a serious, permanent neurological disorder to result from every 300,000 doses of DPT. Thus, with the annual doses administered, there will be approximately two cases of paralytic disease and at least fifty (50) permanent neurologicl injuries that follow. These occur at no fault on the part of the provider or the producer of the vaccine. This is an annual year-in and year-out toll that is inevitable if we are to maintain an immunized population.

When serious injuries occur from any one of the vaccines, the emotional and financial toll for the families involved is severe. The financial stress begins immediately and it is difficult for any family to manage these costs. These costs are continual and often will extend over the lifetime of the victim. If a financial settlement is reached under the tort process, it is usually six to eight years after these costs have begun compounding. Such a tedious legal recourse prolongs this stress for those children and their families who are the innocent victims of the system.

The Academy has spent a number of months negotiating with the parents' group, Dissatisfied Parents Together, to reach agreement on the provisions of this bill. We found that they had many strong concerns that went beyond our original concept of the legislation. We came to realize that their concerns were real and based on their difficult experiences and they similarly came to appreciate the validity of some of our concerns. We know that there are other interested parties that will speak out on this subject and they should be heard. We are confident that out of these hearings can come an excellent piece of legislation that can improve our management of vaccine injuries. The time may come when research will be able to provide us with clean, perfect, and reaction-free vaccines. However, we should not have to wait for that day to give us relief from these sad instances.

At the present time, there is no avenue for compensation for vaccine injuries except in the tort process. In some instances these have resulted in huge windfall settlements while in others the victim may be unable to cope with the tedious tort process and no settlement is reached. In other instances there has been injury and significant expense, but there may not be prospect for a settlement large enough to justify the great deal of work needed by a lawyer to bring action.

Nevertheless, the constantly increasing burden of large vaccine injury settlements has had serious adverse effects on vaccine supply. The number of vaccine producers has been sharply reduced in recent years and the cost of vaccine has increased dramatically. Both of these effects can be related in part to the burden of liability the vaccine producers are carrying at the present time. The result is that we now have only one source of supply for polio, measles, german measles, and mumps vaccine and only three sources of supply for DPT vaccine. This is certainly not a competitive situation, which is typical of the American way, and it does not give one a sense of a secure supply.

We know that a real concern of the Congress will be in the cost of a compensation program. We have seen the estimate of the Congressional Budget Office (CBO). We have not seen the details of their calculations, but we believe that the program can be put in place for much less than CBO estimates. The Academy commissioned a cost study by a respected Washington firm which found the projected costs to be less than one-fourth the CBO estimates and these are probably high. I would like to call attention to four variables in our study. Our study reflects the cost of institutionalization of victims that are completely and totally disabled for a normal lifespan up to seventy-three (73) years as well as figures for a reduced lifespan of forty (40) years. While conclusive data is not available on longevity for these individuals, I suspect that the lower lifespan is more nearly correct. If this is true, our estimates can be reduced accordingly. Secondly, the large cost of the compensation program for the first two years is based on a "grandfather" provision which extends retroactivity back some twenty years. We feel that the estimate for actual cases under this provision is high. It is based on each of the past twenty (20) years having produced the same calculated number of injuries each year and each of these cases being able to document the source of the injury and being capable of proper adjudication after this period of time. If this is true, and we have reason to believe so, our estimate can be further reduced by a considerable amount.

Third, our report calls attention to the fact that the estimates are based on the total cost of the program on the assumption that 100% of the claimants will opt for pursuit under the "new" compensation system. While this may be the best method for calculating an estimate, it is certainly not a realistic appraisal of what may happen under an optional system. And finally, the report calls attention to the fact that there is a considerable real cost in operation at the present time that we have not been able to calculate. The present liability costs under the tort process is incorporated into the present day costs of the vaccines. That cost involved in the vaccine could be reduced in proportion to the acceptance of a compensation system. A small indication of that cost is in the fact that the budget for the federal immunization program had to be increased $7,00,000 for the next year simply to maintain the immunization level in the public sector alone. There are other costs that are hidden in the medicaid program, crippled children's program, and other government programs in providing care for disabled children. Let us again emphasize that the estimates provided are for total cost and not all of these costs are new costs.

While this could be looked upon as simple compensation legislation to take care of another instance of product liability, let me again stress that the justification lies in the fact that this is the only product, to my knowledge, whose use is required by law. This is a unique situation that is deserving of special remedies.

While we are asking the Congress to assume a new responsibility in providing a system for compensation in these special instances, it is not an untested idea. Variations on this idea have functioned for several years in most of the Western European nations and in Japan. Many of these nations are less capable of extending these benefits to their citizens than is this great country.

We have spent many hours debating some of the features that have gone into the writing of this legislation. It would be well to mention here some of those features that required particular consideration and give some explanation for them.

#1: The legislation provides for an optional system. It could be argued that a mandatory system could be more easily administered and the cost estimates could be developed more precisely. However, we had a great concern that the enactment of such a mandatory system would hold up under the test of constitutionality. It is certain that it would be argued that a mandatory system deprived the individuals of their access to court if that access were desired.

#2: The legislation requires a prompt settlement of claims. This is fundamental to any improved system that is devised.

#3: The law mandates an obligation to pursue improved vaccines. This obligation arises now only through competition in the marketplace.

#4: The legislation requires the reporting of reactions rather than the present voluntary reporting. It is hoped that mandatory reporting will develop more exact data of the actual occurrence of reactions.

#5: The legislation makes provision for realistic awards. It is expected that with the awards being realistic, and with the system giving prompt settlements, there will be an incentive to accept the option of going into this system for settlement.

The Academy appreciates this opportunity to present to this committee and to the Congress our interests and our concerns on the entire question of vaccine injury. We recognize that the problems involved here are not simple and that the answers likewise cannot be simple and direct answers. Yet we are convinced that working together with Congress we can provide an answer for most of these problems. We are convinced that the time is at hand when we must reach a direct and equitable resolution of a problem that has been building for a number of years. The problem is real. The costs of a resolution are not exorbitant. The cost of continued neglect can be much greater.

Senator **Hawkins**. Thank you, Dr. Smith.

Dr. King, could we hear from you now, from the Association of State and Territorial Health Officers?

STATEMENT OF STEPHEN H. KING, M.D., STAFF DIRECTOR, HEALTH PROGRAM OFFICE, DEPARTMENT OF HEALTH AND REHABILITATIVE SERVICES, STATE HEALTH OFFICER FOR THE STATE OF FLORIDA, AND SECRETARY-TREASURER, ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS

Dr. **King**. Madam Chairman, my name is Stephen King. I am a physician, State health officer for Florida, and secretary-treasurer of the Association of State and Territorial Health Officials.

I am pleased to appear before you today to discuss Senate bill 2117. There are really two reasons for my being here. The first is that in the last 6 months this bill has been carefully reviewed by public health staff in the Florida Department of Health and Rehabilitative Services. It has kept our attention for a number of reasons. One, of course, is our responsibility for the large number of infants and children who receive vaccines and the vital human potential they represent for our State. In the public sector alone, Florida administers more than 855,000 doses of vaccine that are purchased with public funds, primarily to children under 7 years of age. The total number of doses for the combined public and private sector service delivery exceeds 1.7 million. That is 1.7 million potential situations which could come under the provisions of this bill. Florida, indeed, has a tremendous stake in both the content and the ultimate effect of this bill.

The second reason for my being here today is to represent the Association of State and Territorial Health Officials. Members of the association hold the ultimate responsibility for prevention and control of all vaccine-preventable diseases in their States. It would be difficult to find a group in this country, I believe, who places greater importance on the value of immunization in protecting the health of children. This point is a part of my prepared comments, Madam Chairman. I have attached at the back a resolution passed by the association in 1978, and I would like to have it included for the record, if I could.

Senator **Hawkins**. Without objection.

Dr. **King**. It is certainly in support of what this bill is attempting to do.

Progress in immunization is, by nature, a slow and gradual process. The gains which this country has made since 1977 in raising immunization levels to their current high points are the results of expanded State legislation, intensified efforts by State health departments, and increased Federal funding and support.

Incidentally, in Florida, Federal support for the imported cases of measles and the resultant outbreaks has been essential in our efforts to control it.

It has not happened easily or quickly. This national success is mirrored in Florida. In 1977, Florida reported 308 cases of measles to the Centers for Disease Control. In 1981, Florida passed the comprehensive immunization law requiring immunization coverage for all children in all grades. Due in large part to this law and its enforcement, we have one confirmed case this year so far.

Recent surveys of school records in Florida revealed that 97 percent of all children entering public and private schools in kindergarten and first grade were adequately immunized against the childhood diseases. Immunization levels for children in higher grades are nearly as high, though they do remain a problem for us. Our levels for all schoolchildren are believed to be the highest of any point in the State's history.

Yet, even as we congratulate ourselves on our successes, we must remember that these levels are fragile and these levels are transient. Many factors could influence our ability to maintain these levels, and there are a number of factors. Among them are vaccine price, parental support of our programs, and the participation of the private medical community.

We are aware that there are rare occurrences of adverse reactions to these immunizations. Since our Nation is so large, these occurrences are also numerous. These reactions may lead to tragic and disabling medical conditions. Even as technology improves the quality of the immunizing material and the numbers of adverse reactions hopefully drops, there may remain some level of reaction which is unavoidable if society continues to realize the very great benefits that I believe immunization programs offer.

In our current legal environment, it appears that victim compensation for these adverse medical outcomes is difficult. Expenses for the cost of litigation for both plaintiff and defendant are enormous. Deserving victims may not be adequately compensated. Occasionally, as a result, parental concerns may lead to questions of the continuation of our programs, as we heard this morning—programs which I personally feel are among our society's most valuable and most important.

This proposed bill, therefore, is a response to an evident need for a more efficient and fair system of compensation for victims of childhood vaccine injury. We vaccinate all children to protect not only themselves, but we also do it to protect the community from disease. I believe we owe compensation to those persons medically injured for the public good.

Health professionals in State and Federal arenas, as well as in the private sector, have been searching for an answer to the question of compensation for vaccination injuries for over a decade. Remember, this resolution was passed in 1978. This bill is the first national effort toward a comprehensive solution to the permanet problem posed by risks inherent in the administration of all childhood vaccines.

The association and the State of Florida laud this effort as a positive public health measure with potential benefits for both individuals, health agencies, and the general public.

I need to say there are some portions of the bill that my association and the State feel need some attention. I would like to see a more exact definition, for instance, of the medical events following vaccinations which qualify for compensation. It is, after all, those medical injuries relating directly to the effects of the vaccine which led originally to this proposed legislation. Also, there is the issue of true negligence, lost wages, and pain and suffering and we have heard already a good deal about that, I think, as to the questions that have come up.

Of course, the final concern that I would like to discuss today very, very briefly is the potential effect on the cost of vaccine and what impact this bill will have not only in cost of the administration of the program, but the difficulties on program administration itself. I think all of these problems can be dealt with, but they are there and need to be acknowledged.

I stand ready to offer the services of members of the association and of the State of Florida to assist you in dealing with these questions. Our support for the concept of compensation for inadvertent vaccine injury is unquestioned. Our support of you, Senator Hawkins, is great in your interest on this bill. Our desire now is to fully answer the questions raised as they will affect millions of American children yet to be immunized.

Every year more than 3.1 million children are born in this country. Each one of them needs the protection offered by vaccination. For the vast majority of infants, this means a series of vaccines, and I won't go into that. However, it adds up to 25 million doses of vaccine administered annually in the United States to small children alone. Immunization of older children and adults adds another 10 million doses.

In closing, I believe this bill is an excellent beginning to the century-old problem of vaccine injury compensation. There are pressures which surround this issue. They are longstanding; they are powerful; and they are conflicting. For the sake of the great number of potentially affected children in this generation and the next and the next, we must give this bill both our support and also very careful, very reasoned attention during its legislative process.

Thank you, Madam Chairman.

[The prepared statements of Dr. King and the Association of State and Territorial Health Officials follow:]

STATEMENT BEFORE THE U. S. SENATE COMMITTEE ON LABOR
AND HUMAN RESOURCES, MAY 3, 1984

STATEMENT OF STEPHEN H. KING, M.D., STAFF DIRECTOR,
HEALTH PROGRAM OFFICE, DEPARTMENT OF HEALTH AND REHABILITATIVE SERVICES,
STATE HEALTH OFFICER FOR FLORIDA AND SECRETARY-TREASURER,
ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS

I am pleased to appear before you today to discuss S. 2117, the National Childhood Vaccine Injury Compensation Act. There are two reasons for my being here. The first is that for the last six months, this bill has been carefully reviewed by Public Health staff in the Florida Department of Health and Rehabilitative Services. It has kept our attention for a number of reasons. One, of course, is our responsibility for the large number of infants and children who receive vaccines, and the vital human potential they represent for our State. In the public sector alone Florida administers more than 855,000 doses of vaccine that are purchased with public funds, primarily to children under seven years of age. The total number of doses for the combined public and private sector service delivery exceeds 1.7 million. That is 1.7 million potential situations which could come under the provisions of this bill. Florida, indeed, has a tremendous stake in both the content and the ultimate effect of this bill.

The second reason for my being here today is to represent the Association of State and Territorial Health Officials. Members of the Association hold the ultimate responsibility for prevention and control of vaccine-preventable diseases in their states. It would be difficult to find a group in this country who places greater importance on the value of immunization in protecting the health of children. (See Attachment I)

Progress in immunization is, by nature, a slow and gradual process. The gains which this country has made since 1977 in raising immunization levels to their current high points are the results of expanded state legislation, intensified efforts by state health departments, and increased Federal funding. It did not happen easily or quickly. This national success is mirrored in Florida. In 1977, Florida reported 308 cases of measles to the Centers for Disease Control (CDC). In 1981, Florida passed a stringent and comprehensive immunization law, requiring immunization coverage for children in all grades. Due in large part to the enforcement of this law, Florida has reported only one confirmed measles case to CDC in 1984.

Recent surveys of school records in Florida revealed that 97% of all children entering public and private schools in kindergarten and first grade were adequately immunized against the childhood diseases. Immunization levels for children in higher grades were nearly as high. Our levels for all school children are believed to be the highest of any point in the State's history.

Yet even as we congratulate ourselves on our successes, we must remember that these levels are fragile and transient. Many factors could influence our ability to maintain these levels -- factors such as vaccine price, parental support, and the participation of private medical practitioners.

We are aware that there are rare occurrences of adverse reactions to immunizations. Since our nation is so large these occurrences might be considered to be numerous. These reactions may lead to tragic and disabling medical conditions. Even as technology improves the quality of the immunizing material and the numbers of adverse reactions decrease, there may remain some level of reaction which is unavoidable if society continues to realize the very great benefits immunization programs offer.

In our current legal environment it appears that victim compensation for these adverse medical outcomes is difficult. Expenses for the cost of litigation for both plaintiff and defendant alike are enormous. Deserving victims may not be adequately compensated. Occasionally, as a result, parental concerns may question the continuation of these programs -- programs which I feel are among our societies most valuable and most important.

This proposed bill, therefore, is a response to an evident need for a more efficient and fair system of compensation for victims of childhood vaccine injury. We vaccinate all children to protect themselves and the community from disease. ! believe we owe compensation to those persons medically injured for the public good. Health professionals in state and federal arenas, as well as in the private sector, have been searching for an answer to the question of compensation for vaccination injuries for over a decade. This bill is the first national effort toward a comprehensive solution to the permanent problem posed by risks inherent in the administration of all childhood vaccines. The Association and the Florida Department of Health and Rehabilitative Services laud this effort as a positive public health measure with potential benefits for both individuals, health agencies and the general public.

There are some portions of the bill that may need further attention. I would like to see a more exact definition of the medical events following vaccinations which qualify for compensation. It is those medical injuries relating directly to the effects of the vaccine which led originally to this proposed legislation. Also, the issues of true negligence, lost wages, and pain and suffering should be carefully examined as to their proper place in this bill. A final concern includes the potential effect on cost of vaccine and what impact that will have on program administration.

I stand ready to offer the services of members of the Association and the staff of the Florida Department of Health and Rehabilitative Services to assist in dealing with these questions. Our support for the concept of compensation for inadvertent vaccine injury is unquestioned. Our support for Senator Hawkins as she demonstrates her interest and concern over this child health issue is firm. Our desire now is to fully answer the questions raised by certain provisions of the bill as they will affect millions of American children yet to be immunized.

Every year, more than 3.1 million children are born in this country.

Each one of them needs the protection offered by vaccination. For the vast majority of infants, this means a series of three vaccines -- diphtheria, tetanus, and pertussis (DTP), measles, mumps, and rubella (MMR), and polio (TOPV) -- given in a series of five clinic visits before the second birthday. This adds up to nearly 25 million doses of vaccine administered annually in the U. S. to small children alone. Immunization of older children and adults add another 10 million doses.

In closing, I believe S. 2117 is an excellent beginning to the century-old problem of vaccine injury compensation. The pressures which surround compensation are long-standing, powerful, and conflicting. For the sake of the great number of potentially affected children in this generation and the next, we must give this bill both our support and careful attention during its legislative course.

Thank you.

Attachment I

Statement of the
Association of State and Territorial Health Officials
on Vaccine-Related Injuries

Since barriers to the success of important preventive health programs have occurred due to the problem of liability alternative to the Torts system within law, the Association of State and Territorial Health Officials recommends that:

1. A uniform national compensation system be developed to cover the necessary costs of the occasional circumstances of non-negligent vaccine-related injury to those who participate in any immunization program encouraged as a matter of national health policy;

2. The Secretary of Health, Education and Welfare should review the detailed studies and recommendations already made available to him, and forthwith recommend to Congress the administration and funding of a compensation system for those occasional individuals found on substantive review to be non-negligently injured from receipt of licensed vaccines, and regardless of whether the vaccine program provider is a public health agency, or private provider who has been enlisted in the interests of national policy;

3. That the Federal government published model duty-to-warn forms add the availability of compensation and the means by which review of requests may be initiated, as well as the full information on the benefits of the vaccine to both individual participants, and the whole society, as a means of encouraging informed participation in national immunization initiatives; and

4. Congress pass the necessary statutes to authorize and appropriate for the establishment of the proposed national compensation system, stressing that its purpose is one of social justice for those who participate in valuable national programs for the good of all as well as for their own individual benefit.

Approved by Executive Committee
August 24, 1978
Port Ludlow, Washington

Senator HAWKINS. Thank you so much, Dr. King.

Dr. Salk, we look forward to your testimony. You are a famous doctor.

STATEMENT OF JONAS SALK, M.D., THE SALK INSTITUTE FOR BIOLOGICAL STUDIES, SAN DIEGO, CA

Dr. SALK. Madam Chairman, I have been listening very carefully to testimony that has been given thus far, and I wish to offer for the record what I have prepared in writing. I would like to emphasize the point that one of the available poliomyelitis vaccines [oral live virus vaccine] causes paralysis in a small number of instances and that an alternative vaccine exists [injected killed virus vaccine] that does not cause such injury. Another vaccine that is the cause of injury is the pertussis component of DPT. To make my point I would like to put the following question to the committee: If two pertussis vaccines existed, one of which causes injury and the other does not, would the latter not be the one that would be used to avoid such injury? I want, therefore, to bring to your attention the fact that the live poliovirus vaccine now in general use, causes more than the two cases per year of vaccine-associated paralysis, as has just been stated by Dr. Smith. Such cases occur to the extent of about 6 to 10 cases per year and not only in children who are vaccinated but in adults who are contacts of vaccinated children and also in community contacts. Accumulated over the period of time since the live poliovirus vaccine has been in use, more than 200 cases have accumulated over the period of the last 20 years.

In view of the fact that a killed poliovirus vaccine exists which does not cause vaccine-associated paralysis, I would suggest that the way to deal with polio-vaccine-associated injuries would be to exclude indemnification for polio-vaccine-associated injuries from the legislation so as to create an incentive to avoid such injury since the killed virus vaccine is equally effective in protecting the vaccinated individual and the community from the development of outbreaks of poliomyelitis.

This issue has been a subject of considerable discussion for quite some time. These facts were brought prominently to attention more than a decade ago. The conditions that have prevailed in the past as far as questions of equivalence of effectiveness of the killed virus vaccine which is safe as compared with the live virus vaccine that does cause injury, have now, in 1984, been resolved because of advances in the science and the technology of killed virus vaccine manufacture. If the science and the technology of pertussis vaccine manufacture was similarly advanced then the use of an improved vaccine would be introduced rather than indemnification. My simple plea is that indemnification is not necessary for solving the problem of polio-vaccine-associated injuries.

[The prepared statement of Dr. Salk follows:]

Statement
on
NATIONAL CHILDHOOD VACCINE INJURY COMPENSATION ACT

by

Jonas Salk, M.D.
The Salk Institute for Biological Studies
Post Office Box 85800
San Diego, California 92138

Prepared For

The Committee on Labor and Human Resources
The United States Senate
Washington, D.C.

3 May 1984

I am here to offer my views on legislation now being considered to provide compensation by the United States government to victims of vaccine-related injuries. I believe that such victims should receive fair and adequate compensation without the necessity to engage in uncertain lawsuits with producers of biologics, and their insurers, who understandably will use their power to defend their interests which differ from that of the victim.

I have two serious concerns with regard to such legislation:

- One is the removal of the incentive for manufacturers and the scientific community to improve existing vaccines--for example, the pertussis component of the DPT vaccine.
- The other is the removal of the incentive to change policy when equally effective but safer vaccines already exist--for example, poliomyelitis vaccine.

Therefore, such legislation should provide for:

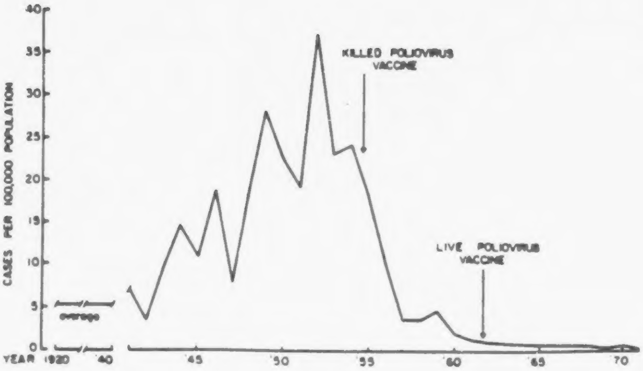
- Encouragement of research and development of vaccines free of the untoward side effects for which indemnification is to be provided.

With regard to pertussis, further research and development is underway. However, in the case of poliomyelitis two vaccines exist, one of which has the property of causing a small but definite number of cases of paralytic poliomyelitis each year and the other of which is free of this property. Figure 1 shows the effect of vaccination on the incidence of poliomyelitis in the United States, and Figure 2 shows that since 1973 more polio cases have been caused by the live virus vaccine as compared to the number caused by the naturally occurring wild virus. The issue surrounding these observations has been discussed many times and will, in due course, be resolved by appropriate changes in policy or by legislation.

In summary:

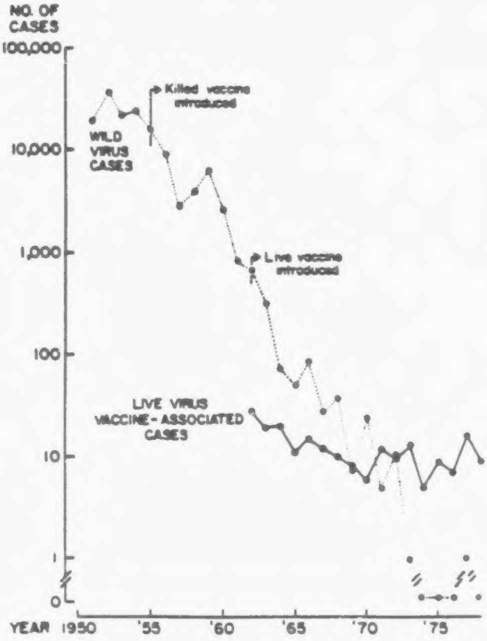
> I am of the opinion that such legislation as is being proposed is necessary but should be written in such a way as to provide the kinds of safeguards that would avoid the need for indemnification as a remedy for vaccine-associated injuries.

Figure 1



Incidence of total reported poliomyelitis in the United States, 1920-1971.

Figure 2



Comparison of the annual number of cases of paralytic poliomyelitis due to wild poliovirus disease and of cases of live virus vaccine-associated disease in the U.S.,1951-1978. After 1969, the indicated cases of wild poliovirus disease are only those of domestic origin.

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February 17, 1984

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RE: S-2117 --
National Childhood Vaccine
Injury Compensation Act

Dear Senator

I am writing concerning Senate bill 2117 (National Childhood Vaccine-Injury Compensation Act) which I understand is currently being considered by the Labor and Human Resources Committee. Although I support no-fault compensation for vaccine injury that cannot be avoided, one must carefully consider the wisdom of legislating compensation for injuries that are unnecessary. Use of oral, live poliovirus vaccine carries the inherent risk of inducing paralytic disease, whereas an alternative vaccine is available that is equally effective but carries no such risk. It is my opinion that live poliovirus vaccine should not be included in legislation concerning compensation of vaccine injuries until careful consideration has been made of the legal, ethical, and economic implications of such action.

Oral, live poliovirus vaccine is also called OPV or Sabin-type poliovirus vaccine. Every year, the Centers for Disease Control receive an average of nine reports of permanent paralysis caused by the live poliovirus vaccine. It is likely that additional cases occur but are not reported. Approximately one-third of the cases are infants who received live poliovirus vaccine, one-third are young adults (primarily parents) who come in contact with vaccinated infants, and one-third are in other children or adults who come in contact with vaccinated persons. Those people who are paralyzed after coming in contact with a vaccinated person have never consented to be vaccinated and are usually unaware they are at risk of contracting paralytic disease.

Nine cases annually seems like a small number, but it must be examined in context. In the first place, these cases involve permanent paralysis or loss of life, injuries that are particularly tragic and costly to society when they occur in infants or young parents. Secondly, disease due to naturally occurring polioviruses has essentially been eliminated from the United States: except for imported cases and one outbreak of poliomyelitis imported into the unvaccinated Amish community in 1979, virtually all cases of paralytic poliomyelitis since 1974 have been caused by the live poliovirus vaccine. Live poliovirus vaccine now causes more disease than the virus against which it is used.

The occurrance of vaccine-associated poliomyelitis is a result of instability inherent in the live poliovirus vaccine; such cases will continue to occur as long as the vaccine is used. This situation would be tolerable, and no-fault compensation might be reasonable, if there were no alternative vaccine. Another vaccine is available, however, that is equally effective in preventing paralytic poliomyelitis in individuals and in controlling the disease in the community. Killed poliovirus vaccine is prepared from viruses that are dead and cannot cause disease; this vaccine, given by injection, is also referred to as inactivated poliovirus vaccine (IPV) or Salk-type vaccine.

Killed poliovirus vaccine brought poliomyelitis under control in the United States in the 1950s and early 1960s. Live poliovirus vaccine was then introduced and became the vaccine of choice for a variety of reasons; use of killed poliovirus vaccine gradually declined. After hearings in the Health Subcommittee of the Senate Labor and Public Welfare Committee in September, 1976, when testimony was given by Dr. Jonas Salk, poliomyelitis vaccination policy was reviewed by a special committee of The Institute of Medicine in March, 1977. The committee included physicians, lawyers, manufacturers, clergy, politicians, and consumer representatives. The committee recommended (1) continued use of live poliovirus vaccine for primary immunization of infants, (2) use of killed poliovirus vaccine for certain specific circumstances, and (3) a review of poliomyelitis vaccination policy in 5 years (March, 1982). No such review by a broadly representative body has yet been undertaken, although many of the circumstances considered by The Institute of Medicine committee in 1977 no longer apply in 1983.

As you might expect, many lawsuits have been filed against individual physicians and vaccine manufacturers as a result of live virus vaccine-associated paralytic poliomyelitis. In addition, however, cases are now pending against the American Academy of Pediatrics and the U.S. Government for their actions regarding live poliovirus vaccine.

I urge the Labor and Human Resources Committee to reevaluate poliomyelitis immunization policy before including oral, live poliovirus vaccine in a vaccine-injury compensation bill.

For your further information, I have enclosed the abstracts of three papers published in 1980 that discuss immunization against poliomyelitis in the United States.

Sincerely,

Darrell Salk

Darrell Salk, M.D.
Assistant Professor of
Pathology and Pediatrics

DS:gmm

Enclosure

Senator HAWKINS. Thank you, Dr. Salk. We're glad you came, also.

Mr. Dodd, an attorney from Torrance, CA?

STATEMENT OF ANDREW DODD, ATTORNEY, WARD, DODD & GRANT, TORRANCE, CA

Mr. DODD. Yes, Senator. I am briefly going to summarize what I have already submitted to the committee.

That is that there are candidates in our society today allegedly suffering from pertussis injury, pertussis vaccine-related injury, who are not candidates for litigation. This bill presents an alternative for those children.

I, myself, over the past 4 years have seen three of these children, and I think it is very important that the committee understand that, in that sense, I am not biased, because this bill will, in my opinion, benefit at least three children who have undoubtedly meritorious claims but are not appropriate candidates for litigation.

Any litigator in the United States today who is presented with an allegedly vaccine-related injury must face two issues. The first issue is who manufactured the vaccine. One of the issues that has dealt with this bill, of course, requires mandatory reporting by the administering physician of vaccine manufacturer identity. However, that has not been true over the past 40 to 50 years. Consequently, there is a serious problem in the legal profession in attempting to obtain identification of manufacturers involved. If you do not have manufacturer identification, you then in most States in the United States have no lawsuit.

Now the people who fall into that category would benefit greatly, in my opinion, by this bill, because they would have an opportunity to seek compensation for what is an extremely devastating injury to a family unit in terms of finances.

With regard to the pertussis vaccine-injured children, that injury presents in many ways. One of the ways that it presents in is a child with a mental capability which never exceeds 18 to 24 months, no matter what the chronological age is. You have a child in that instance who is basically uncontrolled; who may be partially controlled by medication, although not necessarily; a child who will require a sheltered environment for the rest of that child's life; a child whose quality of life may, we hope, be somewhat improved by the application of rather substantial sums of money.

The other issue faced by any litigator with a vaccine-injured child is the question of medical causation. Dr. Brandt from HHS has briefly discussed that, and he was talking about the difficulty of establishing a causal relationship between vaccination and injury. This, of course, is an issue which litigators must face every day.

With regard to pertussis vaccine-injured children, who are that group that I am most familiar with, there are cases which, because of other possible causes, while they are very meritorious and while they certainly meet the ethical constraints that are pertinent to any attorney practicing in this area insofar as being legitimate claims, they may be in the position of being weak medically, on the medical causation side, and, consequently, parents of those types of children do not have access to our court system. I believe that these children would also benefit very greatly by the compensation aspect of this bill.

The balance of this bill, relating to the questions of reporting and data collection, relating to the mandates to the Secretary to make investigations, these things are utterly unique. These are not parallel enactments that pattern after something that we could now do in the law. These are very important because they relate to culpability.

In order to show, if we can, that vaccine manufacturers have been negligent in the manufacture of pertussis vaccine, we must have records and we must have the ability to identify manufacturers.

Dr. Smith, who I know has worked many hours on the bill, one of the things that he prepared in his statement today was that possibly 15 to 50 vaccine-related injuries occur a year without fault on the part of the manufacturer. Now that, of course, is something that I would respectfully take exception with the good Dr. Smith on.

In any event, the question of whether or not manufacturers are liable for these injuries is not something that we could say that a very distinct trend has developed in the courts to determine. It still remains to be seen to what extent, for instance, the manufacturers of pertussis vaccine are culpable. As several of the defense attorneys who are seated in this room in back of me will confirm, there has never been a concession by a drug manufacturer that pertussis vaccine is particularly dangerous or that they bear any culpability under the law.

Each one of these cases, I assure the Senator, is competently defended. There are competent expert witnesses on each side. When you face litigation, it is very important that the public understand that we don't necessarily always have these wonderful results that we all learn from Perry Mason. It is a rigorous kind of thing to do, and there are people who don't fit into that category.

Now to speak to some of the questions, to take the remainder of my time to speak to some of the questions the Senator has raised, would parents choose this system? I think there are—I know of three sets of parents myself who would. I think the answer is clearly yes, people would choose this system.

If this bill were to become mandatory to require this kind of mandatory administrative procedure for adjudication of claims, which I understand the Senator to have indicated that some of the potential cosponsors of the bill have expressed an interest in, I must, unfortunately, indicate that I would do all in my power at that point to oppose the legislation, and I believe that the parents that I represent throughout the United States would feel likewise.

The net effect of that proposal, although it may be quite unintentional, is going to sweep what we believe to be the activities of the drug manufacturers with regard to pertussis vaccine under the rug. It is going, in effect, although again it may not be intended, to act as a bailout for the drug manufacturers in regard to pertussis immunization.

There are estimated to be some 30 to 40 cases presently pending in the United States on the question of pertussis immunization. To destroy those cases by passing a mandatory legislation, I think would be entirely inappropriate, I would submit.

I was very pleased to hear Dr. Smith mention this. As the academy has identified, there are serious constitutional questions to doing that. You are talking about taking away from a child the right to a jury trial. In the case of a pertussis-injured child, you are talking about taking the right of a minor who is also a retarded person, taking away the right for a jury trial. I submit that that would not be acceptable to many people that I know.

One last point that Dr. Brandt raised—and, of course, the communication of ideas by the use of word of mouth is not an exact science, and I may have thought that I understood Dr. Brandt to say things that he did not say, but I thought he said that the administration is concerned that the passage of this bill could lead to a lack of public confidence in immunization policy. I think the truth of the matter, Senator Hawkins, is that this committee presently is the sole and leading safety valve for what many counsel feel is an incredible scandal of incredible proportion. This committee provides a forum for people of opposing views to come together and talk about these problems. The transcripts of this committee have indicated opinions of a wildly divergent nature.

We have an accusation, I believe, in the records of this committee that even for a television station to put this issue on the air is journalistic malpractice. The point of it is, and what drives people to make those kinds of statements is, that this whole issue has become polarized. There are people on one side and people on the other. This committee, I believe, has provided the safety valve for this issue. It is very much to the credit of this committee.

The real, clear, and present danger in this issue is that debate will be silenced; that there will be no discussion in the press about this issue; and that ultimately, the information that is coming slowly but surely in the court system in the United States about specifically pertussis manufacture will break, the public will be enormously upset, in my humble opinion, and we run the danger there that you are going to have a lack of acceptance of immunizations that are appropriate.

For instance, people may, if they learn about pertussis vaccine, if they determine in their own mind that it is an outmoded product, that the design of the product is some 53 years of age, if they determine they don't want their children to have that, and if that is permitted in their State by law, we run the risk that those parents may become confused and also try to deny diphtheria and tetanus vaccination. Diphtheria and tetanus, as I am sure the members of this panel know better than I do, are not something to fool around with. They are an extremely dangerous series of childhood illnesses.

If we stop this debate, if legislation is not passed, then we are going to leave it again in the laps of the litigators. The litigators are doing their best, Senator Hawkins, but our access to information is certainly short of CDC; it is short of DOB; it is short of FDA. Why those people have not chosen to exercise access into all of the information available, I don't know, but the suggestion that this committee is somehow going to contribute to the lack of public confidence, I really respectfully submit is a complete reverse of the truth.

Thank you.

[The prepared statement of Mr. Dodd follows:]

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IN REPLY PLEASE REFER TO
FILE NO.

The Honorable Orrin G. Hatch
United States Senate
Committee on Labor and Human Resources
Washington, D.C. 20510

In re: S.2117, The National Childhood Vaccine Injury
Compensation Act

Testimony of Andrew W. Dodd, Esquire

Dear Senator Hatch:

Thank you for your kind letter of April 24, 1984.

I have been asked to comment upon the appropriateness of S.2117 from the perspective of a litigator with some experience in cases of post vaccine pertussis encephalopathy.

In this regard I should note at the outset that I very much favor the legislation under consideration by your Committee, both from a professional perspective and on a philosophical basis as a member of this society and as the parent of pediatric immunization age children.

On this latter point, the philosophical perspective, it is my feeling that the recognition implicit in the legislation, that there exists a serious problem with pertussis immunization, is an appropriate legislative finding, one which has been much too long in coming.

There was a time, not too long ago, when I was of the opinion that the mere recital to appropriate authorities in the health care delivery system of the bold-faced facts with regard to pertussis vaccine would, surely, be sufficient to bring about change in the manner in which this product is in daily use.

After three years of letter writing I no longer believe in this approach.

Therefore, I applaud the efforts of this Committee with regard to the preliminary fact finding process, especially those efforts of The Honorable Paula Hawkins.

On my first point, a litigator's perspective, my view is perhaps best explained by a brief summary of the manner in which a typical suspected case of pertussis vaccine damage is handled by this firm.

Typically initial investigation of these cases involves, in part, the following steps:

1) In most states of the United States, with the possible exception of California, it is an absolute condition precedent to litigation that the identity of the manufacturer of the pertussis vaccine in question be established.

This "manufacturer identification" has proved to be a most difficult aspect of these cases inasmuch as it is clearly not the practice of the physicians in this country to note in a child's medical chart, or elsewhere, such identification.

Indeed, one landmark case in the 60's on this product was reportedly lost, in part, because no such manufacturer identification was forthcoming.

2) Assuming that manufacturer identification is forthcoming, which is not always the case, the next step is that of establishing medical causation.

In this regard it is important to note that there is no single "test" to determine whether or not a child has been damaged by pertussis immunization.

Rather, the process by which such a diagnosis is rendered involves, in part, a quite complicated and laborious process of examination of each and every medical record ever generated with respect to a patient plus a battery of various diagnostic tests.

Inherent in this process is the fact, which I frequently see, that inadvertent errors often creep into a patient's records.

Once these two steps are accomplished it then becomes necessary to make a determination as to whether or not a particular child's claim is a proper candidate for litigation.

This is not an easy decision to make, especially in view of the fact that attorneys involved in this field, most certainly the ones that I am acquainted with, are quite cognizant of the fact they are operating as a "Court of last resort", ie., there is nowhere else, under the present tort system, for parents of pertussis vaccine effected children to go.

As against this judicial fact of life counsel must balance the facts inherent in his own professional practice, the expense and rigors of litigation and the various ethical constraints inherent in the practice of law, most especially the mandate that counsel shall not accept more cases than he has the time and resources to prosecute.

This balancing of various considerations has lead to, at least in my own practice, a kind of legal "triage" wherein cases without extremely solid and convincing drug manufacturer identification, and medical causation, must be turned down in favor of cases that are "stronger" in the evidentary sense.

The net effect, therefore, of this "triage" process is that cases which undoubtedly are meritorious, and which meet ethical constraints regarding valid and appropriate claims must, regrettably, be turned aside, or at least delayed, in favor of "stronger" claims.

As against this process of screening the legislation under consideration would, in my view, greatly assist in the resolution of the problems I have briefly outlined hereinabove inherent in the traditional tort system.

That is, as I perceive the effect of this legislation, counsel involved in the area of pertussis immunization litigation would be provided with a choice, either to pursue traditional litigation or to proceed by the alternative method provided for in the bill.

Inasmuch as the bill under consideration does not require drug manufacturer identification, nor does the same require the claimant to meet rigorous evidentiary standards with regard to medical causation, the proposed legislated alternative therefore presents a "real" choice to parents faced with pertussis vaccine effected children.

It is the provision for such a "real" choice which persuades me, from a litigator's perspective, that the subject bill is both appropriate and necessary.

Indeed, on a very personal level, I should be remiss if I did not disclose to this Honorable Committee that it is my intention, should the bill under consideration be enacted, to file claims on behalf of three children whose claims, in my opinion, are not appropriate candidates for traditional litigation.

Respectfully submitted,

Andrew W. Dodd

AWD/dc

Senator Hawkins. Thank you, Mr. Dodd. I personally appreciate those remarks, having been accused of the very things you are talking about.

Dr. Alan Nelson of the American Medical Association?

STATEMENT OF ALAN R. NELSON, M.D., AMERICAN MEDICAL ASSOCIATION

Dr. Nelson. Thank you, Madam Chairman.

My name is Alan Nelson. I am a practitioner of internal medicine in Salt Lake City, UT, and I am also a member of the AMA board of trustees.

Madam Chairman, the AMA has over the years strongly urged immunization of children and has long supported public health grants to States to assist in immunization programs. The AMA encourages and supports State-mandated childhood vaccination requirements and continued research into the development of new and approved vaccines. The AMA Auxiliary has also developed and implemented major public education programs encouraging appropriate immunizations.

The beneficial results of this Nation's immunization activity are clear. For example, through the development and widespread availability of vaccines, polio has been virtually eliminated.

We are fully aware, Madam Chairman, of the injuries and illnesses that can result from the administration of vaccines. Even when there is no negligence in the manufacture or administration of a vaccine, scientific evidence indicates that there is a predictable incidence of serious injuries that will inevitably occur in a certain small number of cases.

Such cases are, indeed, small in relation to the total number of doses administered. But, regardless of the rarity of these tragic events, any serious adverse reaction is a matter of crucial concern to one who is directly affected.

Our tort system provides a remedy for persons injured by negligent conduct of another. The problem confronted in the context of vaccine administration is that an injury may result even when no one has committed a negligent act.

The moral problem for society arising from such injuries is that most States require pediatric vaccinations as a condition to school entry. Is it fair to require children to undergo vaccinations and then deny compensation in those rare instances of injury? Is it fair to leave compensation for children to innovations in tort theory that find liability even when there was no negligence? This is the dilemma that has faced and continues to face our society concerning vaccine injury cases.

The AMA has actively participated in the pursuit of fairness for children injured seriously as a result of mandated pediatric vaccinations. We have also been concerned about liability problems for vaccine manufacturers and for those who administer vaccines. In seeking this fairness, we advocate solutions that will continue to encourage parents to have their children immunized. We also seek a course of action that will preserve a ready supply of reasonably priced vaccines—a goal that has moved farther from reach as the number of vaccine suppliers declines and vaccine prices increase as a result of product liability litigation.

We must also assure continued research not only into improvements in vaccines that are currently available, but we must assure continued research into new vaccines for diseases for which there is no prevention now, or perhaps even for diseases for which the cause has not yet been determined.

The AMA in 1983 convened a special Ad Hoc Commission on Vaccine Compensation, on which I had the privilege to serve as chairman, as a forum to examine all aspects of the vaccine injury compensation and to provide recommendations for appropriate legislative remedy. In addition to the AMA, nine other organizations were represented on the commission. These organizations included the American Academy of Pediatrics, the Pharmaceutical Manufacturers Association, the Institute of Medicine of the National Academy of Sciences, Centers for Disease Control, and the National Conference of State Legislatures. All of these organizations designated a member of our commission.

Madam Chairman, the commission has recently completed its report, and this report is appended to our full statement. The report of the commission is now being circulated to the organizations that were represented on the commission, so that each organization can react to the policy positions embraced in the commission's recommendations. Last week the board of trustees of the American Medical Association adopted the report of the commission.

The commission's goals were four:

To identify and equitably compensate persons injured by severe reactions to pediatric vaccines;

Second, to assure the appropriate vaccination of all children;

Third, assure the continued development and availability of pediatric vaccines; and

Fourth, assure the continued participation of physicians and other qualified persons in the administration of pediatric vaccine.

The report presents 13 major recommendations, including a recommendation calling for a Federal legislative program for the appropriate compensation of persons seriously injured as a result of State-mandated vaccinations and a recommendation that such a compensation system must be the exclusive remedy of claimants and not merely an alternative to remedies currently available.

The program envisioned by the commission report would involve a no-fault claims review process and would permit the Federal Government to recover from a negligent party amounts it pays on claims.

At this time I would like to present the views of the AMA on major features of Senate bill 2117.

First, the Government program is an optional remedy. A major feature of S. 2117 is the establishment of a Federal compensation program as an alternative to the traditional tort remedy rather than being the sole source of compensation for vaccine-related injuries. Permitting claimants to continue to bring tort actions against manufacturers and providers will not achieve desired goals in our view, since sufficient protection is not provided from the increasingly high expense of litigation that is driving manufacturers' costs up, costs that have been asserted as forcing companies out of vaccine production.

Beneficial legislation should strike a fair balance between the desirable goal of compensating the victims of serious injuries and the need for vaccine-producing companies to operate in an environment with some measure of protection from the extremely high legal costs in this complicated and threatening area of law.

Madam Chairman, the commission tried very diligently to get a handle on the degree of current legal activity against those who administer and produce vaccines. It was very difficult to do so. As a matter of fact, we were unable to come up with any kind of hard numbers.

However, an attorney who deals extensively with this kind of problem estimated in his report to the commission that in the Chicago area alone 40 to 50 suits are estimated to be filed charging vaccine-related injury.

Private tort remedy as an option, however, would not promote the desired goal of removing existing barriers to achieving the necessary goals of providing for continued availability of vaccines at reasonable cost and maximum immunization coverage of our population.

The vaccine injury table: the bill contains a vaccine injury table that lists in great specificity a large number of compensable events and time periods for onset of those events. Many are too nonspecific and do not constitute a reliable clinical indication. The system could be flooded.

The American Medical Association strongly recommends against having compensable injuries listed in the legislation. Identification of compensable events through administrative procedures may be a more desirable alternative.

Surcharges on vaccine manufacturers: We are concerned that the surcharge method of financing called for in Senate bill 2117 will only accelerate the already high cost of vaccine since it adds to current costs by virtue of adoption of a new system of compensation.

Because the entire population benefits from immunization, not just those immunized, a more appropriate financing system might be one that ultimately relies on general revenue funding.

Other concerns: In addition to these major concerns, questions are also raised relating to the immunizations covered, statute of limitations, provisions as set forth in the bill relating to compensation for loss of earnings, and definition of maximum feasible potential.

We commend you, Senator Hawkins, for seeking development of a means to assist children who are seriously injured through the administration of mandated vaccines. We urge the committee to consider the recommendations of the commission on vaccine compensation submitted with our testimony. We believe these recommendations could provide a framework for a beneficial solution to the vaccine injury compensation problem. We would be happy to work with this committee in developing a program accomplishing our mutual goals.

While S. 2117 also addresses these issues, it continues the present tort system that has resulted in serious problems in this field. For this and other reasons contained in our statement, we are opposed to enactment of Senate bill 2117 as it is currently written.

Madam Chairman, I would be happy to answer any questions.

[The prepared statement of Dr. Nelson follows:]

STATEMENT
of the
AMERICAN MEDICAL ASSOCIATION
to the

Committee on Labor and Human Resources
United States Senate

Presented by

Alan R. Nelson, M.D.

RE: S. 2117 - the National Childhood
Vaccine-Injury Compensation Act

May 3, 1984

Mr. Chairman and Members of the Committee:

My name is Alan R. Nelson, M.D. I am a physician in the practice of internal medicine in Salt Lake City, Utah. I am a member of the AMA's Board of Trustees. With me today is Harry Peterson, Director of the AMA's Division of Legislative Activities.

The American Medical Association is pleased to be at this hearing to present its views on vaccine compensation issues and on S. 2117, a bill that would establish a new federal program to provide compensation to persons injured as a result of receiving vaccine immunizations.

AMA and Immunization

Mr. Chairman, the AMA has over the years strongly urged immunization of children and has long supported federal public health grants to states to assist in immunization programs. The AMA encourages and supports state mandated childhood vaccination requirements and continued research into the development of new and improved vaccines. The AMA Auxiliary has also developed and implemented major public education programs encouraging appropriate immunizations.

The beneficial results of this nation's immunization activity are clear. Today, through the development and widespread availability of vaccines, polio has been virtually eliminated. According to the Centers for Disease Control, the incidence of mumps has fallen from 121,550 cases as recently as 1971 to 3,285 last year, and cases of measles have declined from 75,007 in 1971 to 1,436 in 1983.

We are fully aware, Mr. Chairman, of the injuries and illness that can result from the administration of vaccines. Even when there is no negligence in the manufacture or administration of a vaccine, scientific evidence indicates that there is a predictable incidence of serious injuries that will inevitably occur in a certain small number of cases.

Such cases are indeed small in number in relation to the total number of doses administered. For example, polio contracted from oral polio vaccine is estimated to occur once in 3.2 million doses, leading to an estimated 5 cases in a year. Encephalitis following DTP vaccine administration is estimated to occur 3.2 times per million doses leading to an estimated 43.2 cases per year. Encephalitis following measles vaccination is estimated to result in about 10 cases per year. Deaths due to anaphylactic shock from all vaccines is estimated to be one in ten million doses for a total of five to six cases per year. Other adverse events, such as peripheral mononeuropathy following DTP vaccine, occur very rarely, probably too rarely for even one case annually.

Regardless of the comparative rarity of these tragic events, any serious adverse reaction is a matter of critical concern to one who is directly affected.

Our tort system provides a remedy for persons injured by the negligent conduct of another. The problem confronted in the context of vaccine administration is that an injury may result even where no one has committed a negligent act.

The moral problem for society arising from such injuries is that most states require certain pediatric vaccinations as a condition to school entry. States mandate such immunization because of the epidemiologic fact of "herd immunity," i.e., all of society benefits from vaccination against communicable diseases--not just the vaccine recipient. Is it fair to require children to undergo vaccinations, and then deny compensation in those rare instances of severe injury? Is it fair to leave compensation for children to innovations in tort theory that find liability even when there was no negligence? This is the dilemma that has faced and continues to face our society concerning vaccine injury cases.

The American Medical Association has actively participated in the pursuit for fairness for children injured seriously as a result of mandated pediatric vaccines, for vaccine administrators, and for vaccine manufacturers. In seeking this fairness, we advocate solutions that will continue to encourage parents to have their children immunized. We also seek a course of action that will preserve a ready supply of reasonably priced vaccines--a goal that has moved farther from reach as the number of vaccine suppliers declines and vaccine prices increase as a result of product liability litigation.

In the process of working towards a solution, the AMA in previous years endorsed the concept of vaccine compensation programs at the state level. The Association developed model state legislation and encouraged support by state medical associations. The Association also supports state or federal legislation that will hold physicians and manufacturers harmless for any vaccine-related injury not caused by physician or manufacturer negligence.

Most significantly, the AMA in 1983 convened a special Ad Hoc Commission on Vaccine Compensation, on which I had the privilege to serve as Chairman, as a forum to examine all aspects of the vaccine injury compensation problem and to provide recommendations for any appropriate legislative remedy. In addition to the AMA, the following organizations were represented on the Commission:

- American Academy of Family Physicians
- American Academy of Pediatrics
- American Society of Internal Medicine
- National Medical Association
- American Association of Public Health Physicians
- Institute of Medicine
- National Conference of State Legislatures
- Pharmaceutical Manufacturers Association
- Centers for Disease Control (HHS)

Mr. Chairman, the Commission has recently completed its report, and the report is appended to our testimony. The report of the Commission is now being circulated to the organizations represented on the Commission so that each organization can react to the policy position embraced in the Commission's recommendations. Last week, the Board of Trustees of the American Medical Association adopted the Report of the Commission, and this Report will now be transmitted to the AMA House of Delegates for its consideration next month.

The Report of the Commission on Vaccine Injury Compensation contains the following recommendations:

1. All children should receive the childhood immunizations recommended by the American Academy of Pediatrics and the American Medical Association.
2. A federal legislative program should be pursued for the appropriate compensation of persons seriously injured as a result of state mandated pediatric immunizations.
3. The proposed compensation system must be the exclusive remedy of claimants and not merely an alternative to remedies currently available.
4. Legislation should create a no-fault claims review process.
5. The federal government should recover amounts it pays on claims from any negligent party.
6. All persons seriously injured as the direct result of required pediatric immunizations should be compensated.
7. The Secretary of HHS should be directed by the implementing legislation to constitute an expert advisory group to define the injuries that would be presumptively compensable under the program.
8. Compensable events should not be defined in the legislation, but should be defined wholly by the expert advisory group and promulgated as an administrative rule, with usual notice and comment period.
9. Awards should include medical and other needed care, rehabilitation, special education, and other strictly compensatory elements not covered by other programs. Any pain and suffering compensation should be limited with the award going only to the injured party.
10. The dollar amount of awards would be based on a formula developed by a second expert advisory committee formed of experts in this kind of economic analysis. These formulas would also be promulgated as administrative rules.
11. The formula referred to above should encourage structured settlements, limit fees going to legal counsel, give preference to regional formulas that give cognizance to socioeconomic differences between regions, and focus on local agencies as the locus for making judgments within the formula as to needs in individual cases.

12. Determinations made by the Secretary regarding a person's eligibility for compensation and the amount of awards should carry a presumption of substantial evidence with respect to any judicial review. Judicial review would be appellate, not de novo.

13. Funding options were considered but no one formula embraced. However, the Commission was concerned about a charge added to vaccines.

S. 2117

At this time, I would like to present the views of the AMA on S. 2117, a bill before this Committee on the subject of vaccine compensation.

Description of S. 2117. S. 2117 would establish a federal vaccine-injury compensation program. It would be a no-fault, elective avenue to compensation on the part of persons suffering from certain injuries caused by designated vaccines who meet eligibility requirements set out in the bill. It is no-fault in that there would be no need for a claimant to demonstrate negligence in order to receive an award, and it is elective in that a person may choose to pursue either the traditional tort remedy in the courts or the new compensation program. Payments to claimants under the latter program would come from a trust fund constituted from surcharges levied on manufacturers of childhood vaccines.

The bill thus provides that any person who has sustained a vaccine-related injury (as identified in the bill) may elect to seek compensation under the program established by the bill as an alternative to filing a tort action for damages in state or federal court.

Petitions for compensation under the program would be submitted to the U.S. District Court for the District of Columbia. Upon the entry of proposed findings of fact and conclusions of law by the special master or magistrate appointed by the Court, or upon entry of a final judgment by the court on the petition, there would be a permanent bar against the filing, or further consideration, of any tort action in any state or federal court arising from the same incident of vaccine administration.

Compensation would be awarded to a petitioner when the following four criteria are met:

(1) The petitioner received any of the vaccines listed in the Vaccine-Injury Table set forth in the bill (whether the vaccine was administered before or after the date of enactment of the bill).

(2) The petitioner sustained or had aggravated any of the illnesses, disabilities, injuries or conditions listed in the Vaccine-Injury Table (whether the illness, disability, etc., occurred or was discovered before or after the date of the bill's enactment).

(3) The first symptom or manifestation of the onset or significant aggravation of any such illness, disability, etc., occurred within the requisite time period after vaccine administration, as set forth in the Vaccine-Injury Table.

(4) The petitioner has not previously collected an award or settlement of a civil action in tort for damages for such vaccine-related injury.

The bill provides that a petitioner contracting polio need not have received polio vaccine to be eligible if the petitioner contracted polio from some other person as a result of oral polio vaccine.

Comments on S. 2117

In these comments we will discuss certain of our principal concerns with S. 2117.

Government program as optional remedy. A major feature of S. 2117 is the establishment of the federal compensation program as an alternative to the traditional tort remedy, rather than being the sole source of compensation for vaccine-related injuries. Given the important goals of promoting the vaccination of children and assuring the ready availability of vaccine to meet that objective, legislation should be fashioned to help achieve those goals. Permitting claimants to continue to bring tort actions against manufacturers and providers will not achieve desired goals, in our view, since sufficient protection is not provided from the increasingly high expense of litigation that is driving manufacuturer costs up--costs that have been asserted as forcing companies out of vaccine production.

Beneficial legislation should strike a fair balance between the desirable goal of compensating victims of serious vaccine injuries and the need for vaccine producing companies to operate in an environment with some measure of protection from the extremely high legal costs in this complicated and threatening area of law. S. 2117 seeks to meet the desirable goal of affording relief to individuals suffering injuries and who otherwise would have no remedy for compensation. By preserving the private tort remedy as an option, however, S. 2117 would not promote the desirable goal of removing existing barriers to achieving the necessary goals of providing for continued availability of vaccines at reasonable costs and maximum immunization coverage of our population.

Vaccine Injury Table. S. 2117 contains a Vaccine-Injury Table that lists in great specificity a large number of compensable events and time periods for onset of those events; the Table is an integral part of the legislation and would be used to determine eligibility for compensation.

The American Medical Association strongly recommends against having compensable injuries listed in legislation. The nature of vaccine injuries militate against listing specific events and time periods for onset in statute; there are too many variables. Identification of compensable events through administrative regulations may be a more desirable alternative. Regulations are more flexible and amenable to changes reflecting new developments in the immunization field and permit the on-going input and advice of scientific experts. In addition to the overall objection to inclusion of any specific Table in legislation, we have reviewed the Table and question the appropriateness of medical events listed and the terminology employed. The legislative format precludes necessary flexibility and application of individualized medical judgment. The rigidity of the legislative approach should be avoided.

Surcharges on Vaccine Manufacturers. The bill does not address the increasing costs of vaccines. We are concerned that the surcharge method of financing will only accelerate the already high costs of vaccine since it adds to current costs by virtue of adoption of the new system of compensation. Because the entire population benefits from immunization, not just those immunized, a more appropriate financing system might be one that ultimately relies on general revenue funding.

Medical Practice Standards. S. 2117 would require the HHS Secretary to issue regulations defining the circumstances under which covered vaccines should not be administered, the circumstances under which administration of a vaccine should be delayed beyond its usual time, and the groups, categories, or characteristics of potential recipients of such vaccine who may be at higher risk of major adverse reaction than the general population.

The required HHS regulations would strongly impact on medical practice and questions of professional judgment and liability. We object to such standards being laid down by the Secretary of HHS.

Other Concerns. In addition to these major concerns, questions are also raised relating to the immunizations covered, statute of limitations, provisions as set forth in the bill relating to compensation for loss of earnings, and definition of "maximum feasible potential."

Conclusion

We commend Senator Hawkins and yourself, Mr. Chairman, for seeking development of a means to assist children seriously injured through the administration of mandated vaccines. While the bill would establish a new compensation system and provide coverage for injuries for which no remedy exists today, it also continues the present tort system that has resulted in serious problems in this field. In this respect, the bill would be very costly and should be changed. Other modifications are also desirable in the new compensation program. For reasons contained in our statement we do not favor enactment of S. 2117 without changes from its present form.

We urge this Committee to consider the recommendations of the Commission on Vaccine Compensation submitted with our testimony. We believe these recommendations could provide a framework for a beneficial solution to the vaccine-injury compensation problem. We would be happy to work with this Committee in developing a program accomplishing our mutual goals.

Mr. Chairman, at this time I would be happy to answer any questions from the Committee.

0609p

REPORT OF AD HOC COMMISSION ON VACCINE INJURY COMPENSATION*

Introduction

During the June 1983 Meeting of the AMA House of Delegates, Board of Trustees Report OO, "National Vaccine Injury Compensation Program (Substitute Resolution 9, I-82)," was adopted. In this report, the Board recommended the convening of a special Ad Hoc Commission "to serve as a forum to examine all aspects of the vaccine injury compensation problem and provide recommendations for any appropriate legislative remedy." Such a Commission was established and members met on two separate occasions: September 12 and November 10, 1983. Commission membership included representatives from the AMA's Board of Trustees, and Councils on Legislation, Medical Service, and Scientific Affairs. Additionally, the following national organizations were represented:

American Academy of Family Physicians
American Academy of Pediatrics
American Society of Internal Medicine
National Medical Association
American Association of Public Health Physicians
Institute of Medicine
National Conference of State Legislatures
Pharmaceutical Manufacturers Association
United States Department of Health and Human Services' Centers for Disease Control

Four vaccine producers also were invited and sent representatives to the Commission's meetings. These included observers as well as experts in pharmaceutical products liability.

At its first meeting, the Commission received data and presentations on the scientific and legal environment in which vaccine producers and immunization programs now must operate. To address the paramount concerns in the most pressing area, Commissioners agreed to focus on state mandated pediatric immunizations. Out of these deliberations emerged the strong recommendation that all children receive the childhood immunizations recommended by the American Academy of Pediatrics and the AMA, with special attention to the timely administration of DTP (diphtheria, tetanus and pertussis).

The Commissioners also agreed that the societal benefits accruing from widespread availability of vaccines and full participation by families in pediatric immunization programs warranted a reassessment of the issues surrounding compensation for vaccine-related injuries. In summary, the Commission defined as its goals the following objectives:

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*The recommendations contained in this report represent the views of the Commission. The participating organizations will each make their own determinations with respect to official endorsement of the Commission's recommendations.

- assurance of the continued development and availability of pediatric vaccines;
- assurance of continued participation of physicians and other qualified persons in administration of pediatric vaccines;
- assurance of appropriate vaccination of all children; and
- promotion of the identification and equitable compensation of persons injured by severe reactions to pediatric vaccines.

The Commission believes that these objectives will be promoted with adoption of the recommendations in this report.

Scientific Background

The Commission agreed that the following table fairly represents the most serious vaccine-related injuries that may arise in vaccinated children or adults contracting the disease by contact with these children:

VACCINE RELATED INJURIES

in the U.S.

Permanent Damage	Estimated Incidence	Estimated Annual Doses	Estimated Annual Cases
Brain damage from the P in DTP	3.2 per million*	13.5 million	43.2
Brain damage from the measles vaccine of MMR	1 per million	9.0 million (includes women of childbearing age)**	10*** 4 (future)**
Paralytic polio from TOPV	1 per 3.2 million	18.0 million	5 (Known)**** nearly all in unprotected adults exposed to children given TOPV
Anaphylaxis (acute medical care only) from any vaccine	1 per 10 million (all vaccines)	50-60 million (all age groups)	5-6 (all age groups

OTA Report

*Brit Med J 282:1563, 1981

**Current "Catch-up" rate; projected to reduce to an annual rate of 4 million

***Modern Medicine 50:122-142 (January 1982)

****1980 Annual Summary MMWR 29 No. 54 September 1981

In the Commission's deliberations it was readily apparent that brain damage and related severe neuropathy arising from adverse reactions to pertussis vaccine are now the most pressing concern. Therefore, deliberation on various compensation alternatives revolved around an analytical model based on the recent pertussis vaccine experience, with projections into future years being made thereon. The Commission did note that clinical investigations of an alternative pertussis vaccine are in progress, but felt the exercise would be more valid if it reflected the nature, number, and extent of injuries reported with the current vaccine. A brief discussion about the pertussis disease and vaccine injury was presented to the Commission and this is included in Appendix A.

Public Policy Considerations

The Commission received information from legal counsel regarding the historical development of pharmaceutical products liability standards in both common and statutory law. In assessing the adequacy of existing legal remedies and describing possible new ones, legislative and court imposed modifications (fault and no-fault) were evaluated. In analyzing the alternative vaccine compensation models that might be devised, the Commission noted several decision-making benchmarks:

1. whether eligibility for compensation is carefully, usually narrowly, defined in both clinical and legal terms;
2. whether there is a reliable and easy system to determine whether negligence may have given rise to an injury;
3. whether the introduction of "no fault" or strict liability elements in any compensation program that would run counter to long-established standards for pharmaceutical products and services liability in this country would reduce the likelihood of acceptance;
4. whether the compensation system is able to identify and compensate injured persons without either unduly penalizing vaccine manufacturers and providers or without removing incentives for safe performance by the same parties;
5. whether costs of a compensation mechanism include: payor administration, payor and claimant advocacy and adjudication (including costs attributable to handling spurious claims), medical and related "compensatory" care;

6. whether consideration is given to offsetting expenses already covered by third party payors;

7. whether annualized costs of care and maintenance are very substantial lump sum awards (as with many civil judgments now) or additive year to year to potentially large sums.

With these key elements in mind, the Commission proceeded in a careful examination of the theories and mechanisms by which some improvement in the existing system of vaccine injury compensation might be undertaken, particularly as it related to mandated pediatric immunization.

Common Law

Pharmaceuticals, including vaccines, are "inherently dangerous products" in the lexicon of modern theories of tort liability. Such products are evaluated under a "negligence standard" when product related injury arises. If no negligence in product design, or production, handling, labeling and administration is discovered, a plaintiff in civil litigation may not prevail.

Our society has maintained this standard for vaccines because of the tremendous benefit flowing to a society free of those diseases for which vaccines are available. Maintenance of this standard recognizes that (1) vaccines cannot be made absolutely safe for all persons, and (2) some persons who are, in fact, injured by a vaccine with no attributable negligence may not have a civil remedy.

A description of the principles and legal standards applicable to vaccine liability cases is set out in the Restatement, Torts 2d (1965) section 402A, comments j and k; comment k provides:

Unavoidably Unsafe Products.

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, not withstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous.

> ...The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Current Legal Environment

Commission representatives noted the following problems attendant on civil litigation, above and beyond the concern that non-negligently injured persons might go without remedies: (1) new theories of liability (e.g., failure to provide adequate information to obtain a valid informed consent) are providing new avenues of recovery, thereby destabilizing the litigation (and risk management) environment; (2) there is widespread unhappiness over the extent of fees going to legal counsel, both plaintiffs' and defendants', with the perception that the funds might be better directed to properly compensating claimants; (3) log jams in the courts and delay in legal process, and damages awarded out of proportion to injury, are destabilizing the tort litigation system and detracting generally from its public credibility and acceptance.

The Commission considered two alternative proposals for improving the existing tort remedies:

- There was some agreement that consensus state-of-the-art statements by an expert group could be influential in assisting potential litigants both in evaluating cases and in reaching equitable settlements early in the legal process. The Commission considered recommending that an expert panel be convened by the AMA and others in the private and public sector to describe (1) the clinical parameters for identifying vaccine-related injury, and (2) the projected care needs of the person and his or her family based on the nature and extent of each injury. These recommendations were carried over into the recommendations adopted as part of a comprehensive legislative proposal.

- The Commission considered recommending imposition by the courts or by state legislatures, of strict product liability on vaccine producers. This would, in effect, move tort remedies for vaccine-related injuries to a "no-fault" base—any injury temporally and clinically among those known to be attributable to the vaccine could be compensable, no showing of negligence by plaintiffs would be required and freedom from negligence would not remove liability from producers. It was noted that the ultimate costs of extending plaintiffs' remedies would be borne by society through increased unit dose costs for vaccines and, quite possibly, by the further flight of manufacturers from vaccine production. This alternative was rejected by the Commission because of questions as to whether the cost pass-through could realistically accommodate the anticipated significant producer cost increases that would arise from increased litigation and an increase in the pool of compensable persons. It also noted that this course of action would not remove the manufacturer's liability and would not meet the goal of assuring continued vaccine availability.

Legislative Options

The Commission considered legislative programs of vaccine compensation that could be pursued: federal law (fault or no-fault), state law (fault or no-fault), and federal law that places affirmative duties on the states (fault or no-fault). In addition, the Commission considered the issues of whether the proposed remedy would be optional, added to the tort remedies now available through the courts, or exclusive, whereby a legislatively imposed administrative remedy would preclude the customary civil litigation. Finally, the Commission focused on the possibility of moving pediatric vaccine injury cases entirely out of the tort system by statute and moving them into a comprehensive statutory program.

Recommendations

By consensus, the Commissioners agreed that a federal legislative program should be pursued for the appropriate compensation of persons injured as a result of state mandated pediatric immunizations. After extensive debate, the following key elements were agreed upon:

1. Exclusive vs. Optional Remedy. There is unanimous agreement that an effective way to assure continued innovation and supply of vaccines, their proper and timely administration and to promote public participation, is to remove the vaccine injury cases from the existing tort system. The proposed compensation system must be the exclusive remedy of claimants and not merely an alternative to remedies currently available. The Commission recommends that the federal government become the substituted defendant for the vaccine producers and providers in all claims alleging vaccine-related injury from pediatric immunizations (DTP, measles, mumps, polio.)

2. Fault vs. No-Fault. The Commission recommends that the legislation provide a no-fault entry to the claims review process. Should negligence on the part of the vaccine producer or provider be discovered in the course of administrative or legal review, the legislation should provide that the federal government can recover any award granted under the program from the negligent party.

3. Scope of Coverage. The Commission recommends that all persons seriously injured as a result of required pediatric immunizations be compensated. The proposed legislation would cover only those pediatric immunizations required by state law.

4. Compensable Events. The Commission recommends that the legislation direct the Secretary of the Department of Health and Human Services to constitute an expert advisory group to define those injuries and adversities that would be presumptively compensable under this program. The Commission recommends that the compensable events not be defined in the legislation, but be defined wholly by expert advisors and be subjected to notice and comment through *Federal Register* publication before final adoption.

5. Extent of Compensation. The Commission recommends that awards include the medical and other needed care, rehabilitation, special education and other strictly "compensatory" elements not covered under other programs. While most Commissioners are opposed to inclusion of "pain and suffering" awards, some agree that this may be a necessary element to enhance the political viability of the legislation. All agree that any "pain and suffering" compensation should be strictly limited and the award should run only to the injured party.

6. Amount of Compensation. The Commission recommends that the specific dollar amounts to be awarded by the Secretary be based upon a formula or formulas developed by an advisory committee to the Secretary comprised of experts with experience in this type of economic analysis. As with the advisory recommendations on the definition of compensable events, the Commission recommends that these formulas be published for review and comment before final adoption.

   There was strong sentiment in favor of the following elements being included in the legislative language that addresses development of formulas for damage awards:

   (1) structured settlements;

   (2) a clear statement of the limits of fees going to legal counsel;

   (3) a preference for regional formulas that give due credence to appropriate socioeconomic differences among regions; and

(4) administrative information gathering that focuses on local agencies as the locus for making judgements within the formulas as to the needs in individual cases.

7. Nature of Judicial Review. The Commission recommends that the legislation provide that the Secretary's determination as to eligibility for compensation and the amount of damages shall enjoy a presumption that "substantial evidence" supports the final judgement. Therefore, judicial review should be appellate in nature and not involve retrial of the facts.

Funding

A variety of proposals have been made as to the manner for funding federal legislation to provide new avenues of compensation to persons injured by participation in the national immunization programs.* The Commission does not have at its disposal the extensive information and resources necessary to adequately evaluate alternatives. It notes that a proposal to place a surcharge on each dose of vaccine administered in this country may not be the wisest, given the Commission's goal of full participation in pediatric immunization programs. The most desirable alternative might draw on trust funds coming from general revenues, thereby giving credence to the societal interest in and benefits from immunization programs without in any way burdening the programs or beneficiaries themselves.

Conclusion

The Commission finds that the medical community believes it can, in fact, identify those persons who have had severe reactions to the state mandated pediatric vaccines. With less then severe, irreversible injuries, the causal connection that medicine can state may be less precise. The Commission also finds great dissatisfaction with existing legal remedies as they pertain to injuries arising from mandated vaccines.

Of all of the armaments of medicine, vaccines offer the greatest potential benefit to the greatest number of persons. They also, however, continue to have statistically predictable incidence of very serious injury for a very few persons. The vaccine injury compensation program proposed here is intended to provide assurances to parents and their children, producers and providers of vaccines, that those who benefit so greatly from the prevention of disease and disability will care for those to whom state mandated immunization introduces disease and disability. This proposal equitably shifts existing burdens in such a way that society can:

*"Reports and Recommendations of the National Immunization Work Groups", submitted to the Office of the Assistant Secretary for Health, March 15, 1977. S. 2117 (98th Congress, 1st Session), "National Childhood Vaccine-Injury Compensation Act;" Congressional Record, Vol. 129, pp. S16612-S16621, November 17, 1983.

- be assured of continued development and availability of pediatric vaccines;
- be assured of continued participation by physicians and other qualified persons in the administration of pediatric vaccines;
- be assured of the continuing appropriate vaccination of all children; and
- promote the identification and compensation of persons injured by severe reactions to pediatric vaccines.

APPENDIX A

PERTUSSIS

Pertussis -- The Disease

Pertussis (whooping cough) is an acute bacterial infection of the respiratory tract occurring primarily in young children. The exposed non-immunized neonate and young infant are nearly always susceptible, the attack rate approaching 100%.

Despite prompt intervention with antibiotics, neither the course nor morbidity of the disease is altered. (The prime value of antibiotic treatment is to reduce infectibility of the affected individual.) The most frequent, serious complication of pertussis is pneumonia. This complication is responsible for more than 90% of deaths in pertussis victims under three years of age. Neurologic complications include convulsions and coma, sometimes with residual brain damage, due to anoxia. Rare neurologic complications may include subarachnoid or intraventricular hemorrhage, meningoencephalitis, and an unexplained degeneration of the brain cortex. Specific complications are non-reportable, so their incidence is based on small samples. The Office of Technology Assessment of the United States Congress predicts a pertussis disease-related risk of encephalopathy as 8-140 per 1,000 (Compensation for Vaccine-Related Injuries, November 1980). A short review of this subject is given by Prensky (Dev Med Child Neurol 16:539-543, 1974).

The mortality rate with today's care has been reduced to about 5 per 1,000 cases of pertussis. (In 1926-1930, the fatality rate was 39.1 per 1,000.) The reduction in mortality may be attributed to various factors, including more effective management of secondary infections and greater accessibility to acute medical care. As recently as 1948, pertussis was a leading cause of death in children under 14 years of age. The mortality in the most susceptible group, infants, remains very high; 72% of pertussis deaths occur in children under one year of age.

Pertussis — the Vaccine

Immunization against pertussis uses a concentrated suspension of killed whole Bordetella pertussis organisms in a vehicle combined with diphtheria and tetanus toxoids (DTP). Moderately severe reactions to the vaccine occur which may be attributed to the pertussis component. These include convulsions and hypotonic hyporesponsive episodes, each of which occurs with a frequency of 1 per 1,750 vaccinations (Pediatrics 68:650, 1981). Acute encephalopathy following pertussis vaccination occurs with an estimated frequency of 1 per 110,000 vaccinations and residual damage is present 1 year later in approximately one-third of these individuals (BMJ 282:1595, 1981). It is estimated that approximately 50 cases of permanent brain damage might occur each year in the United States if the risk of encephalopathy is the same for each of the five doses in a DTP series.

APPENDIX B

Elements of Vaccine Compensation Program Endorsed by the Commission

1. There would be established within the U.S. Department of Health and Human Services (HHS) an expert vaccine compensation advisory panel.

2. HHS, after mandated consultation with the expert panel, would be required to establish administratively a list of compensable vaccine injuries and clinical criteria for their documentation as vaccine-associated.

3. Eligible parties (as defined in the statute) would file a claim with the Department of HHS.

4. HHS professional staff would review claims pursuant to standards established and determine whether the claimant was injured, whether the injury or disability is within the class of designated compensable injuries, and whether it is vaccine-associated. HHS would have the power of subpoena, examination of the claimant, etc., at its discretion. Claimant would have the right to usual administrative appeal from denial of a claim.

5. Recovery would be limited to economic losses including medical expenses, costs of medical and vocational rehabilitation, wage loss, and any other out-of-pocket losses not compensated by other programs.

6. Once HHS staff had determined that a claimant had a compensable injury, the amount of the award would be determined pursuant to a compensation plan established administratively by HHS on advice of an expert advisory panel. Amounts in dispute would be dealt with within the appeal process.

7. Structured settlements (i.e., payments to be paid over time on a schedule) would be utilized in cases of injury/disability expected to last more than two years.

8. The vaccine compensation program would be an exclusive remedy: all claims for vaccine-associated injury or disability would be made only under the program.

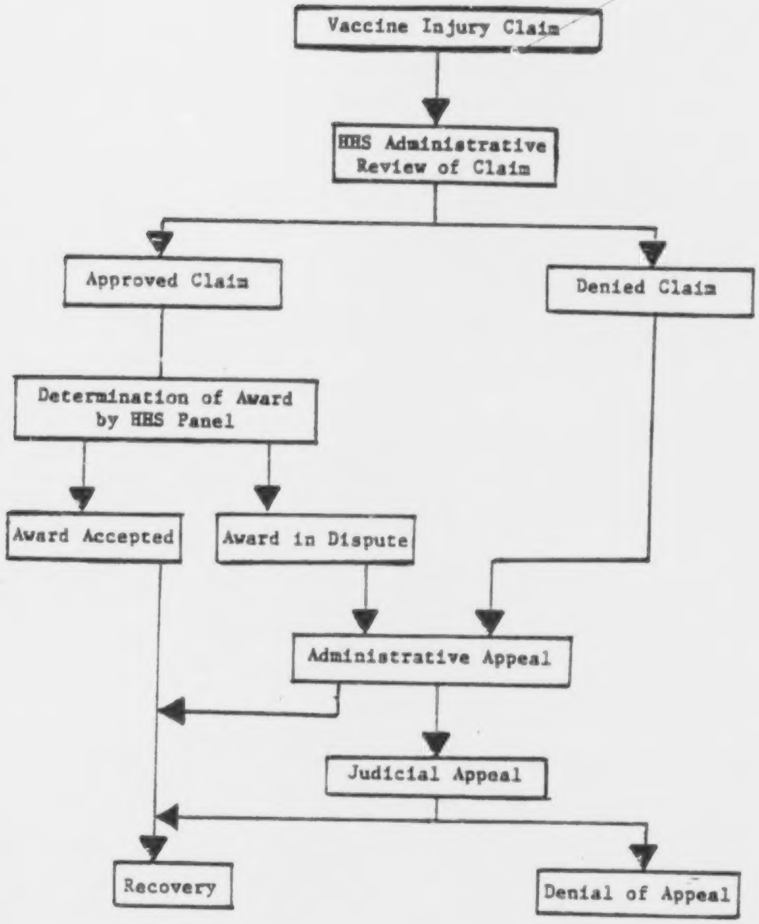
9. When filing a claim for compensation by the government, there would be no need for the claimant to allege or prove fault. Furthermore, the claimant would not be permitted to pursue a tort action.

10. The federal government would have the right to bring an action against a program participant (i.e., vaccine manufacturer or health professional administering the vaccine) to recover amounts paid to claimants and associated expenses resulting from negligent acts or omissions.

11. Except for being subject to suit by the government (#10 above), all individuals involved in the manufacture, distribution, and administration of government designated vaccines would be immune from any legal action by vaccinees or their representatives for injuries and disabilities covered by the HHS program.

12. If a claimant's claim is denied, or the amount awarded is disputed, the claimant may appeal the decision to a federal court after exhausting administrative remedies. The Secretary would enjoy a presumption that substantial evidence supported her decisions; review would not be de novo but limited to a review as to whether HHS had properly interpreted and fulfilled its statutory obligations.

VACCINE COMPENSATION SYSTEM PROCEDURE FLOW CHART


Vaccine Injury Claim
HHS Administrative Review of Claim
Approved Claim
Denied Claim
Determination of Award by HHS Panel
Award Accepted
Award in Dispute
Administrative Appeal
Judicial Appeal
Recovery
Denial of Appeal

Senator HAWKINS. Thank you.

Thank you to the entire panel. I have a lot of questions. I may submit some of them for the record in the interest of time. We will also provide that opportunity for the other Senators, to provide questions that can be answered in writing.

Dr. Smith, you referred to a cost study?

Dr. SMITH. Yes.

Senator HAWKINS. Would you officially provide a copy of that cost study for the record?

Dr. SMITH. Yes.

Senator HAWKINS. Thank you very much.

[The cost study referred to follows:]

ESTIMATED COSTS OF "THE NATIONAL CHILDHOOD VACCINE INJURY COMPENSATION ACT"

12 March 1984

PUTNAM, HAYES & BARTLETT, INC.

I. INTRODUCTION AND SUMMARY

Millions of children are immunized each year against such diseases as tetanus, diphtheria, pertussis, polio and others. These immunization programs protect society from disease epidemics and thus save many children and adults from death and disability. However, these mandatory immunization programs are not without costs. Each year a small fraction of children have severe reactions to vaccines that result in permanent disability and in some cases even death.

Supported by the efforts of the American Academy of Pediatrics and Dissatisfied Parents Together, a group of parents of vaccine injured children, Senator Hawkins has submitted a bill to Congress (S.2117) which would compensate victims of adverse vaccine reactions. The purpose of this report is to estimate the potential costs of this bill.

To evaluate the potential costs of the legislation, this analysis examines the following:

- Cost of compensation per case,
- Total cost of compensation over time,
- Awards in the tort system, and
- Potential impact on the Federal budget. (qualitatively)

In addition to compensating victims of vaccine injuries, the proposed legislation would provide funds for research. However, this report does not attempt to analyze those costs.

There is some uncertainty regarding the life expectancy of these victims. Since life expectancy has a large impact on the expected cost of compensation, we have estimated costs under two life expectancy scenarios:

- o 73 years (base case), and
- o 40 years.

This analysis estimates that the base case average cost of compensation per case will be about $230,000 and the 40 year scenario cost per case will be about $166,000. These estimates include legal fees of 20 percent but excludes administrative overhead which would probably add an additional 5 percent to the cost of the bill. Reimbursement for foregone earnings is by far the largest component of cost, comprising 62 percent of the base case average cost per case and 54 percent of the 40 year scenario cost per case.

The total cost of the program in future years will depend on the form of payment. The bill allows the claimant to choose from among three payment forms: two lump sum payment options and an option which reimburses expenses as they are incurred. Victims will also have the option of choosing either the tort system or the legislative program. However, for the purposes of this analysis, we assume that all victims choose the legislative system. Assuming a 73 year life expectancy, if patients are reimbursed for actual expenses as they are incurred, the payments for the entire program will be close to $86 million per year the the first two years, then drop to $31 million per year in the third year and increase to a steady state cost of $64 million per year by the seventy-third year of the program. If patients opt for either of the two lump sum type payment options, initial costs will be significantly higher -- over $200 million in each of the first two years. However, steady state costs would be $45 million, lower than under an actual reimbursement scenario. Therefore, decision makers looking only at the first thirty years of the program would prefer to compensate victims as costs are incurred because it is cheaper than lump sum compensation in the beginning. However, from a steady state annual cost perspective, either of the lump sum options would be preferred.

If life expectancy is 40 years, annual costs will not only be lower under all cases, but the differences between the options will be less. Costs for both cases in the first three years and at steady state are shown in Exhibit 1. The steady state costs assume that incidence will be constant over time. Actually research in this area is likely to reduce the risk of the vaccine thereby reducing incidence and annual compensation costs.

The cost of the program in the first two years is quite large relative to estimated revenues from the sale of vaccines. Using the base case assumptions the cost could range from two-and-a-half times annual sales revenues in the actual reimbursement scenario to almost six times annual revenues in the lump sum scenario. This could put a substantial initial burden on manufacturers and the Federal government.

As the major purchaser of vaccine, the Federal government would be affected by any changes in the price of the vaccine. It is difficult to estimate how the legislation will affect vaccine prices and therefore the Federal budget because it is uncertain how the costs of compensation under the legislation will differ from the costs of compensation through tort awards.

Relative costs under the two systems depends on a variety of factors including the propensity of people to file claims under each system, the

Exhibit 1

TOTAL COST OF PROGRAM
(Million $)

Payment Option	Year 1	Year 2	Year 3	Steady State
73 Year Life Expectancy				
Actual	85.6	85.7	31.0	64.2
Lump Sum	230.9	230.9	44.9	44.9
Ten Year	205.4	205.4	19.4	44.9
40 Year Life Expectancy				
Actual	77.0	77.1	29.5	39.6
Lump Sum	165.9	165.9	34.2	34.2
Ten Year	149.4	149.4	17.8	34.2

average compensation and range of compensation under each system, and the number of people who would still choose the tort system if a legislative alternative were available. Although these factors are uncertain, the following qualitative observations indicate that costs and therefore the impact on the Federal budget are likely to increase if the legislation is enacted:

- More people are likely to make claims if a legislative package is available.
- The range of awards in the tort system is large, and
- Claimants who expect high tort awards would still have the option of pursuing litigation instead of making a claim through the legislative system.

The remainder of this report focuses on the base case 73 year life scenario and is organized as follows. The methodology used by Putnam, Hayes & Bartlett (PHB) is described in Section II. This section also identifies the assumptions and data sources used in the cost projections. Section III presents the results of the base case cost analysis and reviews awards in several vaccine damage related tort cases. The final section provides a summary of the legislative system costs and compares these estimates to costs in the tort system and discusses possible effects on the Federal budget. Three appendices are also attached. Appendix A contains the computerized worksheets used to estimate costs of the bill. Appendix B presents the National Center for Health Services Research (NCHSR) data used to categorize illnesses and assign medical and rehabilitation costs. Appendix C presents the results of the 40 year life scenario cost analysis.

II. METHODOLOGY

Bill S.2117 provides compensation to victims of vaccine-related injuries for various damages such as medical costs, loss of earnings, special education, and so forth. To simplify the task of estimating the potential cost of this bill, PHB developed the framework shown in Exhibit 2. Reactions to childhood vaccines can range from mild -- a sore arm or one or two days of fever, to severe -- ending in permanent disability or death. The bill would not compensate most mild cases because the minimum compensation limit is $2,500. AAP has estimated that .03 percent of vaccinated children would have a mild reaction that would require short term hospitalization costing roughly $2,500. We use these estimates, and in addition, we rely on three illness categories -- Acute, Chronic, and Death -- to represent the wide range of more serious possible reactions. Cases in each illness category will receive different compensation components. The compensation components are listed for each illness category in Exhibit 2. Compensation can be claimed in any one of three forms, as depicted by the diagram in Exhibit 2.

In defining illness categories and estimating the medical and rehabilitation costs associated with them, PHB relied on work done by the Office of Technology Assessment (OTA)* and the National Center for Health Services Research (NCHSR) of HHS.** NCHSR developed 73 patient scenarios to represent the range of possible immunization reactions

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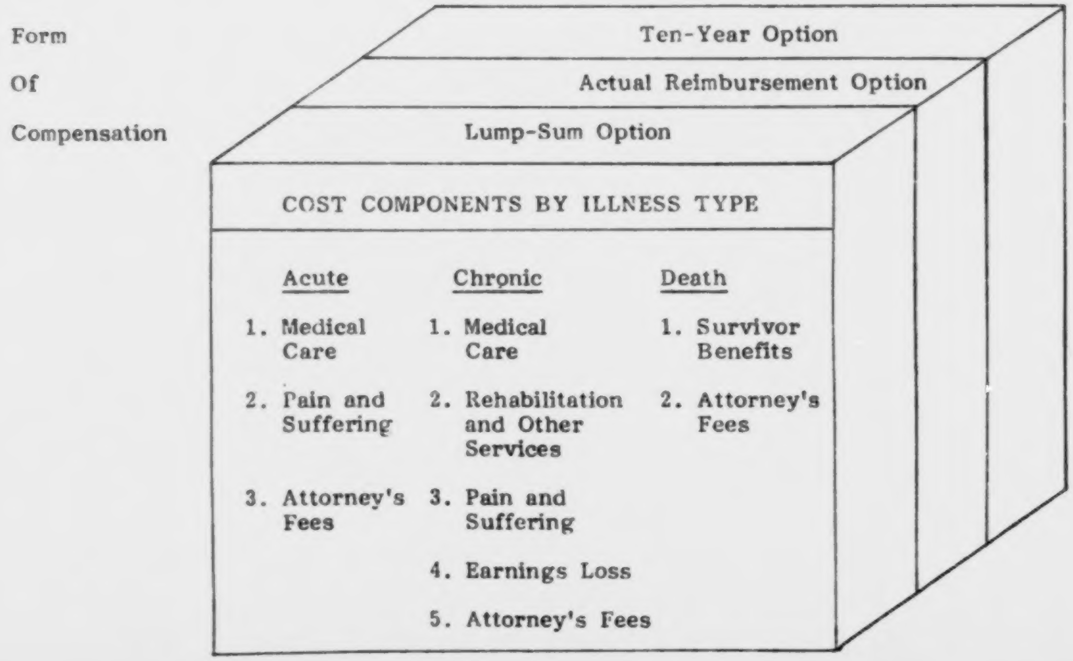
* Compensation for Vaccine-Related Injuries, Office of Technology Assessment (OTA), Table 1, pp. 42-43, November 1980.

** U.S. Department of Health and Human Services, Estimated Economic Costs of Selected Medical Events Known or Suspected to be Related to the Administration of Common Vaccines. "Resource Utilization Profiles." unpublished appendix. April 1981.

Exhibit 2

ILLNESS AND COMPENSATION CLASSIFICATION


Form
Of
Compensation
Ten-Year Option
Actual Reimbursement Option
Lump-Sum Option
COST COMPONENTS BY ILLNESS TYPE
Acute
1. Medical Care
2. Pain and Suffering
3. Attorney's Fees
Chronic
1. Medical Care
2. Rehabilitation and Other Services
3. Pain and Suffering
4. Earnings Loss
5. Attorney's Fees
Death
1. Survivor Benefits
2. Attorney's Fees

and costs. We chose two of these scenarios to define and assign costs to the Acute and Chronic illness categories. "Resource Utilization Profiles" from the NCHSR report for the two selected illness categories are reproduced in Appendix B.

Six separate compensation components can be identified from the proposed legislation:

- Medical Expenses - Reimbursement of all past and actual or anticipated future out of pocket medical costs.
- Rehabilitation, Special Education, Home Care and Other Continuing Services - Reimbursement of any other necessary facilities or care.
- Pain and Suffering - Compensation not to exceed $100,000 for the victim only not the family.
- Earnings Loss - Compensation for anticipated loss of earnings due to disability.
- Survivor Benefits - Compensation to the parents of a victim in the event of vaccine related death.
- Legal Fees - Up to 20-25 percent of total compensation.

As Exhibit 2 shows, not all victims will receive compensation for all components.

Cases in the Acute category are characterized by collapse requiring about a week of hospitalization but resulting in complete recovery. Thus, medical expenses are assumed to occur only in the first year and no rehabilitation or special care costs would be incurred. Medical costs are based on the NCHSR profile "moderate encephalitis, encephalomyelitis, and aseptic meningitis due to DTP Vaccine characterized by collapse and resulting in complete recovery." Compensation for pain and suffering is limited in the bill to $100,000. Since this component would probaby be much less for patients in the Acute category, our analysis assumes an average pain and suffering benefit of $10,000 per case although this may even be high. Earnings loss compensation is not applicable in the Acute scenario because the victim's eventual ability to work will not be impaired. Survivor benefits also are not applicable because the vaccine does not result in death. Legal fees up to 20 percent of total compensation are allowed by the bill if the claim is granted initially, and fees up to 25 percent are allowed if the case is appealed or reviewed. This analysis assumes compensable legal fees are an additional 20 percent of compensation.*

Illnesses in the Chronic category would result in long term disability, such as brain damage, which would require long term medical and therapeutic care and could prevent or limit the victim from entering the work force. Compensation for victims in this category could include reimbursement for long term medical care as well as special education, therapy, and domiciliary care throughout adult life. Cost estimates for these components are based on the NCHSR profile of "severe encephalitis and encephalomyelitis due to the DTP vaccine resulting in psychomotor retardation." Compensation for pain and suffering is assumed to be $25,000 per case in this analysis although this may be low. In addition to these costs, victims in the Chronic category would be compensated for foregone earnings. This analysis assumes that the patient would receive the equivalent $18,200** annually between the ages of 18 and 65. Legal costs are assumed to be 20 percent of total compensation.

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* Some interested parties expect legal fees to be close to 10 or 15 percent.

** $18,200 was the average manufacturing wage in 1983.

Rarely, reaction to an immunization can end in death. In these cases, we assume the child dies within 24 hours of the immunization, and thus assume no medical expenses are incurred. The bill does provide a benefit to the parents of the deceased child of between $300,000 and $700,000. This analysis assumes $500,000 per case. Legal costs are again assumed to be an additional 20 percent.

The estimates for each cost component as described above permit us to develop a cost per case for each illness category. In addition, we assume that the very short hospitalization cases are compensated $2,500 per case. In order to estimate the total cost of the bill in its first year and over time, assumptions in the following areas are also necessary:

- Payment schedule.
- Annual incidence by illness category.
- Number of claims for cases that occurred prior to the enactment of the bill.

The Bill offers the three payment options listed in Exhibit 2:

- "Lump Sum Option" - A lump sum payment to cover all past and future projected expenses.
- "Actual Reimbursement Option" - An initial lump sum payment to cover all prior expenses plus reimbursement of future expenses as they are incurred.
- "Ten Year Option" - An initial lump sum payment to cover prior expenses plus projected expenses for five to ten years with the right to a final determination as to remaining lifetime payments at the end of that five to ten year period. (This analysis assumes a ten year period.)

By definition, the expected net present value (NPV) per case will be the same under each scenario. This is because costs in the Actual

Reimbursement Option are equal to expected costs in the other two options. Annual payments over time, however, can differ significantly as the results in Section 3 show.

Annual incidence by illness category are based on incidence rates from OTA (and AAP for the short term category) and estimates of 1984 dosages from the Congressional Budget Office (CBO). These are shown in Exhibit 3A. The bill also allows any existing cases to file claims during the first two years of the program. The number of retroactive claims is based on estimates of average annual incidence over the last twenty years. We use CBO's estimates of past incidence and assume that 50 percent of cases in the Chronic and Death categories will file claims during the first two years of the program. It has been argued that propensity to claim will be even less than 50 percent due to lack of awareness of the disease's causation and lack of proof. Since Acute cases are limited in duration and have no severe long-term effects, we assume that no past Acute claims will be filed. Exhibit 3B shows these assumptions.

III. RESULTS

Cost Per Case

Exhibit 4 presents the costs per case by cost component and the three more serious illness category. For each category there are three columns:

- Year 1 Costs are costs that occur only in the first year (the year of incidence). These include compensation for pain and suffering and survivor benefits as well as all medical costs that occur in the first year. Furthermore, all attorney's fees are assumed to be paid in the first year.

Exhibit 3A

ANNUAL INCIDENCE 1984 TO FUTURE

	TOTAL*	ACUTE	CHRONIC	DEATH
DTP	131	89	42	0
POLIO	3	0	3	0
MEASLES	6	4	2	0
MUMPS	21	21	0	0
ALL (DEATH)	4	0	0	4
TOTAL	165	114	47	4

Short term hospitalization = 2700**

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* OTA, Compensation for Vaccine-Related Injuries, November 1980. Table 4, p. 51. 1978 incidence is adjusted to reflect lower 1984 dosage using CBO's figures of 48 million doses in 1984 and 72 million in 1978.

** Based on AAP estimate of .03 percent times annual dosage.

Exhibit 3B

INCIDENCE 1964-1983

	TOTAL	ACUTE	CHRONIC	DEATH
Annual	212	147	61	4
20-year total	4240	2940	1220	80
Number of Claims*	650	0	610	40

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* Assuming no claims for Acute illness, and 50 percent from Chronic and Death category file claims.

Exhibit 4

COSTS PER CASE BY ILLNESS CATEGORY
(Constant 1984 dollars)

	ACUTE			CHRONIC			DEATH			
Cost Category	Year 1	Annual	NPV	Year 1	Annual*	NPV	Year 1	Annual	NPV	Weighted Avg NPV
Medical Expenses	$ 3,457	$ 0	$ 3,457	$ 11,818	$ 23	$ 12,589	$ 0	0	$ 0	$ 5,975
Rehabilitation, etc.	0	0	0	9,014	1,479	58,448	0	0	0	16,648
Pain and Suffering	10,000	0	10,000	25,000	0	25,000	0	0	0	14,030
Earnings Loss	0	0	0	0	18,200**	505,471	0	0	0	143,983
Survivor Benefits	0	0	0	0	0	0	500,000	0	500,000	12,121
Legal Fees	2,691	0	2,691	120,302	0	120,302	100,000	0	100,000	38,552
Total	$16,148	$ 0	$16,148	$166,134	$19,702	$721,810	$600,000	$ 0	$600,000	$231,309

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* Calculated by annualizing the NCHSR's present value of costs excluding year 1. A 73-year life was assumed.

** Compensation for lost earnings does not begin until the 18th year and lasts until the claimant is 65.

- Annual Costs are costs that occur annually after the first year of the illness. These include medical and rehabilitation costs (assumed to be constant throughout life) and lost earnings compensation, which is assumed to be earned from age 18 to 65.

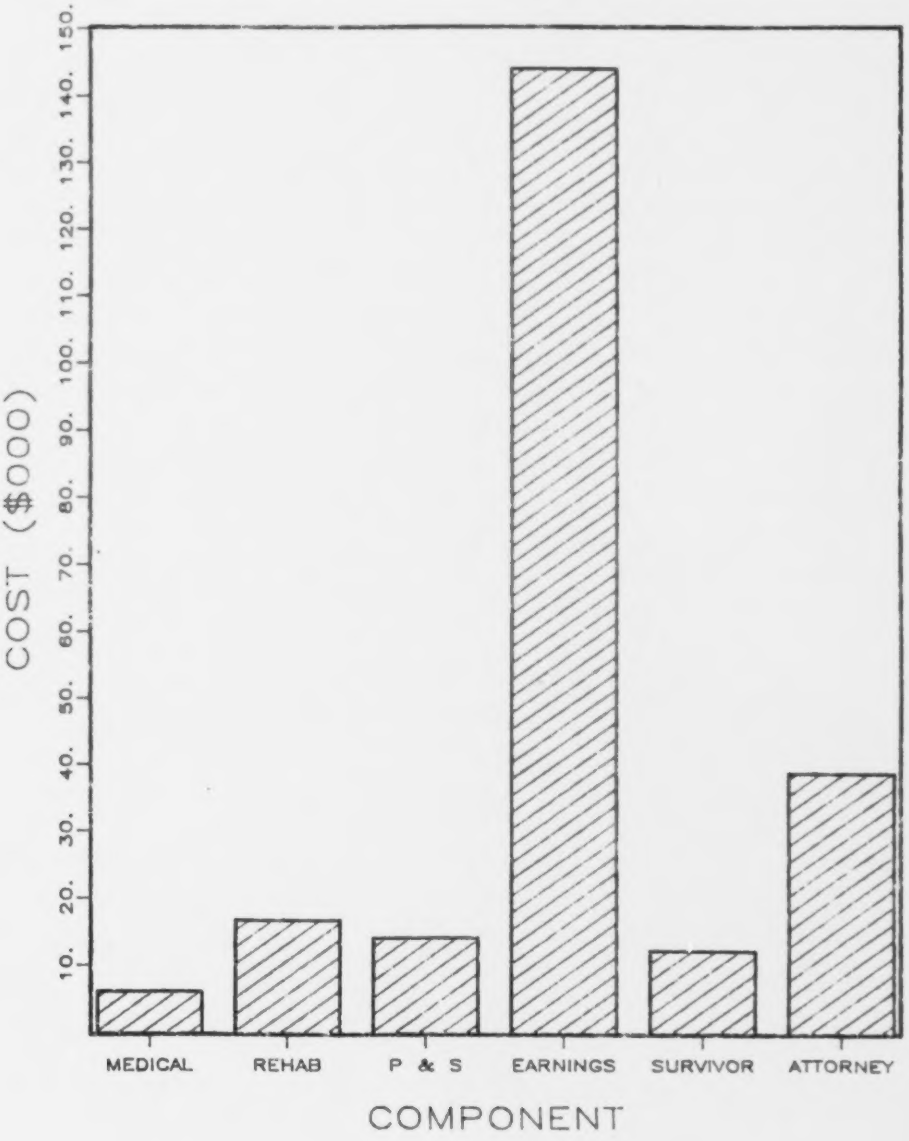
- NPV Costs are the total discounted present value of each compensation component throughout a patient's life. Constant dollars and a real discount rate of 2.5 percent are used. NCHSR used a "differential inflation factor" to increase the present value of medical costs by 15 percent over the entire 73 year period.

Note that all costs for cases in the Acute and Death categories (as well as the short hospitalization category) occur in the year of incidence; only illnesses in the chronic category incur costs over time. As would be expected, cost per case is highest in the Chronic category: $722,000 in present value terms. Total compensation costs for parents of children who die from the vaccine is $600,000. Compensating Acute cases is significantly less expensive, costing $16,000 per case. Since the majority of cases fall into the Acute category (almost 70%), the weighted average cost per case excluding the short stay cases (shown in the last column of Exhibit 3) is $231,000, significantly less than the Chronic or Death category costs. If we were to include the mild short stay cases costing $2,500 per case, the weighted average cost per case would only be $16,000.

The last column in Exhibit 4 and the bar chart in Exhibit 5 show the relative magnitude of each cost component in the bill. Compensation for lost earnings is by far the largest component of the bill's cost; it comprises 62% of the average cost per case. Attorney's fees, at 17% of average cost per case, are the second largest component. Rehabilitation costs are about 7%, pain and suffering costs are 6%, and survivor benefits are 5%. Medical costs are the smallest component, costing less than 3% of the average cost per case.

Exhibit 5

WEIGHTED AVERAGE NPV COST COMPONENTS
(73 year life expectancy)



Total Cost Over Time

Exhibit 6 shows the pattern of expenditures over time under each payment option: actual, lump sum, and ten-year. A list of these annual cash flows is in Appendix B. Clearly, expenditures over time will vary greatly depending on the option selected.* Steady state, the state at which annual costs are constant each year, occurs in the third and tenth year, respectively, for the lump sum and ten year options but not until the seventy-third year for the actual reimbursement option. Exhibit 7 shows the program cost for the first few years and at steady state for each payment option. Under each option, the bill's costs in the first two years are significantly higher than in future years. This is because the retroactive claims are filed and compensated during the first two years of the bill. In the actual cost scenario, the impact of retroactive filing is smaller than the other two options because past claims receive compensation only for past expenses and one-time payments (such as pain and suffering, survivor benefits and attorney fees). Future expenses for retroactive cases are not paid in years 1 and 2 in the actual cost option; rather, they are reimbursed over time as they are incurred.

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* The cash flow estimates for each option assumes that all cases select that option.

PAYMENT SCHEDULE

73 YEAR LIFE EXPECTANCY

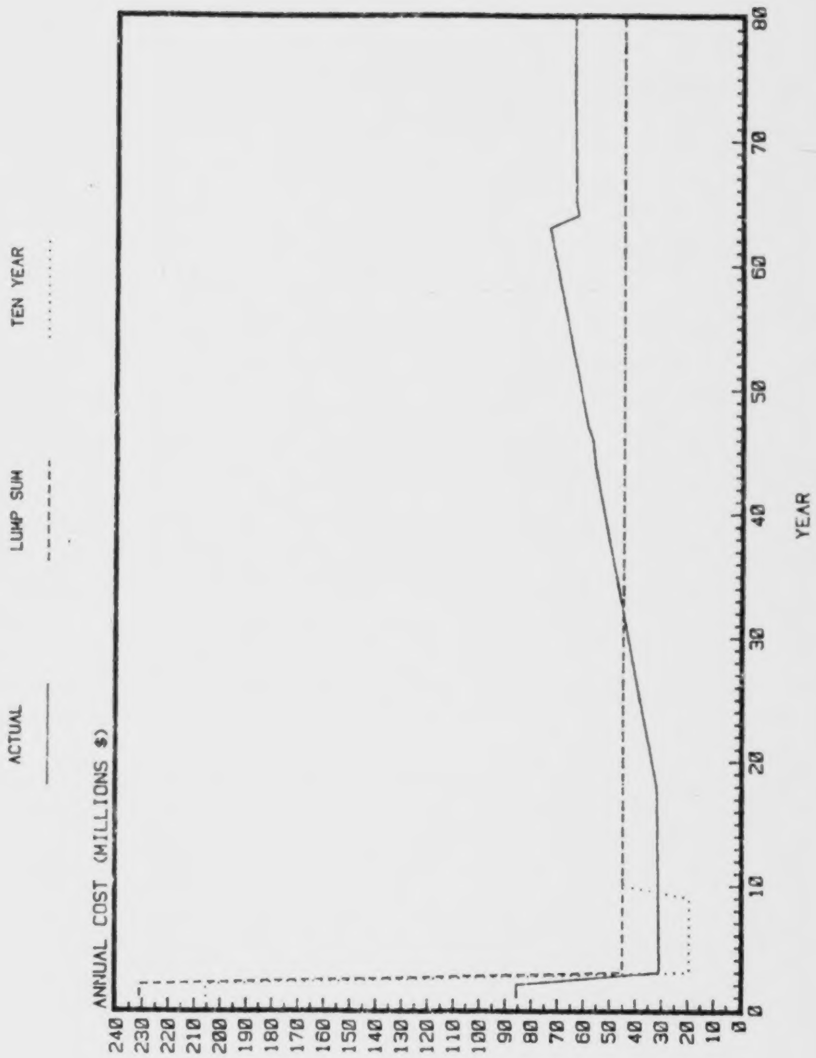

Exhibit 7

TOTAL COST OF PROGRAM
(Million 1984$)

Payment Option	Year 1	Year 2	Year 3	Steady State
Actual	85.6	85.7	31.0	64.2
Lump Sum	230.9	230.9	44.9	44.9
Ten Year	205.4	205.4	19.4	44.9

Tort Compensation

As the eleven cases in Exhibit 8 show, awards in the tort system for victims of vaccine-related injuries vary greatly in size. Compensation in these cases ranges from $150,000 to over $5 million. It is difficult to draw any conclusions regarding average tort awards from such a small sample of cases, particularly since the range is so large. However, if these cases are representative, compensation costs under the tort system are likely to be higher than our estimated average $231,000 per case under the bill. With the exception perhaps of the Larson v. Eli Lilly case ($150,000), however, all of these cases would fit into our Chronic category. Thus, the more appropriate comparison would be with chronic cases which would, using our assumptions, receive compensation of about $600,000 before legal fees under S.2117. Since attorney fees are likely to be greater and more variable under the tort system, it is difficult to predict whether average cost per case for chronically ill patients will be higher under the tort or legislative system. Nevertheless, it is safe to say that individual compensation could reach much higher levels in a tort award or settlement than through legislation.*

IV CONCLUSIONS

This section reviews and discusses the results of the analysis and briefly outlines possible implications of the bill in four areas: cost per case, total cost over time under each payment scenario, cost relative to the tort system, and potential impact on the Federal budget.

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* This would particularly be the case if litigation were to result in punitive damages, which would not be allowed under the legislative compensation option. A recent case suggests that punitive damages may be available for DPT vaccine injuries involving inadequate warning (Morris v. Parke, Davis & Co., 573 F. Supp. 1324 (C.D. Cal. 1983).

Exhibit 8

TORT COMPENSATION

Case	Award	Award Components	Comment
1. Tom v. Allen Continuing Seisure Disorder and Metal Retardation	$5,500,000		Structural Settlement
2. Peifer v. Devitt Brain Damage and Seisure Disorder	$3,050,000	$1,300,000 Future medical cost 1,000,000 Future pain, suffering and disability 500,000 Loss of future earnings 250,000 Past pain suffering and disability	Verdict
3. Wilson v. U.S. Epilepsy and Brain Damage	$2,700,000	Mother - $350,000 Child $407,096/immediately $ 55,000/yr first 10 yrs $ 80,000/yr next 10 yrs $150,000/yr next 10 yrs $413,000/yr life	After Trial Settlement
4. Roarke v. Parke Davis Brain Damage	$1,000,000		Cash Settlement

SOURCE: Jeffrey Schwartz, Esquire, Dissatisfied Parents Together.

Exhibit 8

TORT COMPENSATION (Continued)

Case	Award	Award Components	Comment
5. Anon. v. National Lab Seisure Disorder and Brain Damage	$851,000		Cash Settlement
6. Caron v. U.S. Brain Damage and Convulsions	$656,326	$500,000 for Pain and Suffering	Verdict
7. Holcomb v. U.S. and Richardson Merrill Postpertussis Encephalopathy	$600,000		Settlement
8. Tinnerholm v. Parke Davis Brain Damage and Convulsion	$500,000		Verdict
9. Parke Davis v. Stromsodt Brain Damage and Convulsions	$500,000		Verdict

Exhibit 8

TORT COMPENSATION (Continued)

Case	Award	Award Components	Comment
10. Kindrex v. Merrill National Lab Encephalopathy	$371,000*	$175,000 immediately $ 1,000/month for life	Structured Settlement
11. Larson v. Eli Lilly Recurrent Convulsion Disorder	$150,000		Settlement

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* Present value assuming 63 year remaining life expectancy and 6 percent discount rate.

Cost Per Case

The estimated weighted average cost of the bill per case is $231,000. This cost will be higher if the proportion of Chronic or Death cases is higher relative to Acute cases, and lower if there is a larger proportion of Acute cases.

Replacement of lost earnings is the largest component of this cost. We have assumed that all victims of Chronic diseases will receive 100 percent of the average manufacturing wage throughout their wage-earning years (18 to 65) and that this wage stays constant in real terms. Other victim compensation bills that compensate claimants for lost income* provide only a fraction of lost wages: usually 67 to 80 percent of either actual lost income or an average wage. The expected cost of Senator Hawkins' bill would be reduced if "the generally recognized actuarial principles and projections" referred to in the bill were interpreted to include a wage recovery factor of less than 100 percent. In addition to reducing the earnings component of the bill, this would reduce allowable attorney's fees, which are a flat percentage of total compensation and are the second largest single cost component.

Survivor benefits are large relative to other costs on an actual case basis; (compare $500,000 for those in the Death category to lost earnings benefits for Chronic patients of $505,000). Survivor benefits do not have as large an impact on the weighted average cost per case or on the total cost of the bill, however, because the number of people receiving those benefits is assumed to be small.

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* Legislative proposals have been developed for Asbestos exposure (HR 3175) and toxic substance exposure (H.R.2330, H.R.2482, S.946, H.R.2582).

Total Cost Over Time

This analysis focuses on the cost of compensating victims. Hence, we ignore other costs of the National Childhood Vaccine-Injury Compensation Act such as the broad-based study of risks associated with the vaccines covered by the bill.

Exhibit 6 shows the estimated pattern of cash flows over time. Assuming incidence remains constant over time, costs will reach a steady state by the seventy-third year of the program for the actual cost scenario and much earlier for the other two scenarios. Annual costs under the lump-sum scenario start off very high in the first two years when retroactive cases are allowed to file claims. The annual cost of $231 million in the first two years is five times greater than the steady-state annual cost of $45 million. Under this scenario, steady state is reached in the third year of the program assuming incidence remains constant over time.

Under the ten-year option, annual costs in the first two years are four an a half times greater than steady-state annual costs. In the third year, new cases receive compensation for the expected present value of costs for the next ten years only, so annual costs are at less than steady state. In the tenth year, the initial claimants receive compensation for all future expenses and the cost remains constant at $45 million per year as long as the incidence rate remains the same.

The pattern of actual reimbursement option cash flow starts off high in the first two years, although not as high as the lump-sum or ten-year options, then drops significantly in year three when the retroactive cases can no longer file. Annual costs increase gradually through year 18.

During this period, new claimants are added to the compensation pool each year, yet none receive earnings reimbursement (although, we assume that all retroactive cases do). In year 19, we assume that all claimants who filed in the first year begin receiving earnings loss compensation and the growth rate in annual cost increases. By the thirty-second year, annual costs for the actual cost option are greater than annual costs under the other two options. In the sixty-third year, we assume that the pool of retroactive claimants dies, reducing annual costs. This is a simplifying assumption; in actuality, deaths of these patients would be spread over a longer period and the drop in annual cost would not be as dramatic. The rate of increase in annual cost is slower from year 65 to year 73 as the first claimants reach retirement age and stop receiving earnings loss compensation. We assume that all claimants have a normal 73-year life expectancy, so at year 73, when the first group of claimants dies, incidence equals death rate and the cost of the bill reaches steady state.

Clearly, while the present value cost per case of each option is the same, the annual cash flows over time are very different. Under the lump-sum and ten-year options, the initial costs are extremely high but the steady state annual costs are only 70 percent of the steady state costs under the actual cost scenario. A decision-maker looking at costs for the first 30 years of the program would clearly opt for the actual cost option. On the other hand, decision-makers reevaluating the system 30 years later would wish the initial decision-maker had selected either the lump-sum or ten-year option.

Focusing on the impact of the bill's cost today, the lump-sum option would impose a substantial burden on manufacturers and purchasers of the vaccine if a surcharge were imposed to fund the entire $231 million. Who bears the largest part of this cost depends on how the costs can be passed from manufacturers to purchasers through price increases. This cost in the first two years is almost six times the annual revenues of vaccine manufacturers.* The annual cost of $205 million in the first two years under the ten-year option is over five times annual revenues. The burden of these non-recurring costs could be softened by spreading the cost out over time with a financing mechanism. For example, the bill permits the fund to borrow against the Federal treasury and to repay the debt with interest. An additional problem with the high initial cost is that assessing an appropriate surcharge rate will be difficult.

Initial costs under the actual cost alternative impose a smaller burden on the fund. The annual cost of $86 million in the first two years is just over two times annual vaccine revenues. The steady state annual cost under the actual cost option, however, is 1.6 times current annual revenues compared to the steady state cost under the other two options, which is just slightly more than current annual revenues.

Comparison With Tort Costs

It is difficult to compare costs of legislative compensation to costs in the tort system for two reasons:

- First, the limited available data on tort awards and the wide range of compensation reported in the few cases available make cost-per-case comparisons speculative.

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* Actually, we do not have precise information on annual revenues from vaccine sales. However, knowing that the Center for Disease Control spent approximately $13 million in 1982 and comprised about one-third of the market, we estimate that total sales were about $39 million. This does not include DTP.

- Second, the number of victims who might make claims is unknown but probably will not be the same under each alternative.

Little empirical data is available to make assumptions regarding propensity to claim under a legislative versus legal system. However, it is interesting to note that claims for automobile accident injuries increased 60 percent when no-fault automobile insurance went into effect. This statistic seems useful if we view a legislative system as a no-fault alternative to the tort system. Therefore, even if the average cost per case in the legislative system is less than in the tort system, total costs of the legislative system could exceed the tort system because propensity to claim is higher.

An additional point to note is that the bill as it is currently proposed is not an exclusive remedy for victims of vaccine injury. Victims may choose either the administrative route or litigation. Thus, those potential claimants who expect an award in the tort system that is higher than the bill's compensation (after subtracting transaction costs) could still resort to the tort system.

Of course, factors other than the expected value of an award affect a claimants' decision-making, such as the higher probability of receiving benefits, the speed at which compensation occurs and the magnitude of legal expenses (particularly if fees must be paid up front). Clearly, under a legislative system compensation is more certain, the process is not as lengthy and involved as litigation and legal fees are likely to be lower.

Impact on the Federal Budget

The information currently available does not allow precise quantification of the impact of the proposed legislation on the Federal budget. However, we can qualitatively evaluate the potential costs of the bill by examining the costs the Federal government currently bears as a result of vaccine-related injuries and estimating how these costs might change as a result of legislation.

Costs Currently Borne

The Federal government currently incurs compensation costs in two ways:

- As a purchaser of vaccines, and
- As a provider of social programs.

As a major purchaser of vaccines, it bears some indeterminate portion of the tort and liability insurance costs manufacturers pay and pass on to purchasers through increased product prices. Over the past five years, Federal agencies have bought more than 30 percent of the net doses of many of the most commonly used immunization vaccines that were distributed.* No data is available on what portion of the price the Federal government paid for vaccines covers compensation claim costs. Moreover, it is not clear how the recent high tort settlements, verdicts and expected future claims will affect insurance costs and vaccine prices.

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* Includes only measles, rubella, measles/rubella, MMR, oral polio, mumps, and inactive polio vaccines.

One small manufacturer of DTP vaccine claims the reason it raised its wholesale price in May 1983 from \$3.89 to \$35.00 per 7.5 ml vial was to cover increased liability exposure. This would suggest that at least 89 percent of its current selling price resulted from compensation costs. However, this could be an isolated case as other manufacturers have not followed suit with similar price increases. In fact, over the past ten years, prices for major vaccines paid by Federal agencies have increased, on average, between 6.9 and 25.0 percent per year, with a typical increase in the 8.7 to 13.5 percent range. These increases are not substantially higher than the rate of inflation, indicating that the recent costly tort settlements have yet to radically increase product prices for most manufacturers.

The second way in which the Federal government currently pays vaccine-injury related costs is through various entitlement and social programs such as Medicaid, SSI, maternal and child health block grants, and the Education For All Handicapped Children Act. The primary beneficiaries are children of disadvantaged families. No figures are available to determine how much these programs pay to cover expenses for immunization victims.

Potential Costs if Legislation is Passed

If the proposed bill is passed, the Federal government would see its current obligations for compensating immunization victims change in three ways:

- The cost of the vaccine is likely to change,
- The burden on social programs will probably fall, and

- A new liability will probably be incurred to underwrite deficits of the fund.

The cost impact on the government as a purchaser of vaccines will depend on how the legislation affects the price of the product. Under the legislation, compensation costs will be funded by a surcharge on manufacturers of vaccines. To the extent that manufacturers increase or decrease the price of the vaccine in response to this surcharge relative to the price under the tort system, the Federal government will be affected indirectly because, for many vaccines, it buys almost one-third of the net amount that is distributed. It is difficult to predict which direction product prices will move, particularly since minimal information is available regarding vaccine manufacturers' expectations and actions on tort costs. The variables that will have the major impact on prices are:

- The propensity of people to claim under each system
- The average compensation cost and the range of costs under each system, and
- The number of people who would choose the tort alternative if the bill were passed.

As mentioned earlier, more people are likely to claim under a legislative system because the barriers to making claims, such as high up front costs and long legal processes, are reduced or eliminated. This is particularly true for victims in the short hospitalization or Acute categories who would probably not file tort suits due to high transaction costs and low expected awards but would be qualified to make a claim under the bill. This factor would tend to make costs under the legislation greater than costs under a tort system.

The average compensation per case under the fund is likely to be less than the average tort award. This factor would tend to make costs under the bill less than under a tort system, all other things being equal.

Since the bill does not remove a victim's right to sue, high tort awards would not be eliminated under the legislative scheme. However, the number of people who would file tort suits would probably decline if a legislative alternative were available.

Clearly, these factors can have different effects on the cost of the legislative system relative to the tort system. If the net result is that the surcharge plus the cost of residual litigation is less than the cost manufacturers would expect from litigation in the absence of legislation, product prices would decline with the enactment of the bill. However, since propensity to claim is likely to increase and since the legislation preserves the option of victims to sue, it is more likely that product costs and, therefore, Federal expenditures would increase with the enactment of legislation.

The second way that the Federal government might be differentially impacted is through its social programs. To the extent that victims choose the legislative route, the vaccine-injury costs, such as medical, education, and training expenses for immunization victims, that presently are paid by entitlement and social programs, will be shifted to the compensation fund, reducing the burden on Federal programs. In addition, the incentive to enter the welfare roles because of high medical costs would be eliminated for victims who choose that fund. Hence, such income supports to families would no longer be paid by the Federal government.

The third way in which the Federal budget would be affected by the legislation is through loans to the fund. The bill authorizes the fund to borrow, with interest, from the Federal Treasury if it runs out of money. Therefore, there could be a short-term cash drain on the Treasury that would be paid back in future years. If large numbers of parents elect to take lump-sum payments, the cash deficit that would need to be covered by the Treasury is potentially quite large: a total of $462 million in the first two years. This would be less ($171 million in the first two years) if people tended to choose the actual cost reimbursement option.

[illegible] [illegible]

COST CATEGORY	ACUTE YEAR 1	ACUTE FUTURE PV	ACUTE ANN.	CHRONIC YEAR 1	CHRONIC FUTURE PV	CHRONIC ANN.	DEATH YEAR 1	DEATH FUTURE PV	DEATH ANN.	WEIGHTED AVERAGE NPV/CASE
MEDICAL COSTS										
-Hospital care	$3,004			$10,515						$5,071
-Inpatient specialist	$192			$563						$293
-Inpatient non-spec.	$177			$531						$274
-Outpatient specialist	$26			$53						$33
-Outpatient non-spec.	$58			$156	$771	$23				$304
REHABILITATION COSTS										
-Home modification				$5,560						$1,584
-Physical therapy				$1,567						$446
-Occupational therapy				$992						$283
-Special education					$26,698	$799				$7,605
-Long-term care					$18,313	$540				$5,216
-Equipment				$895	$4,423	$132				$1,515
TOTAL MED. & REHAB. COSTS	$3,457	$0	$0	$20,832	$50,205	$1,502	$0	$0	$0	$22,623
LOST EARNINGS					$505,471	$18,200				$143,983
PAIN & SUFFERING	$10,000			$25,000						$14,030
SURVIVOR BENEFITS							$500,000			$12,121
SUBTOTAL	$13,457	$0	$0	$45,832	$555,676	$19,702	$500,000	$0	$0	$192,758
ATTORNEY FEES	$2,691			$120,302			$100,000			$38,552
TOTAL	$16,148	$0	$0	$166,134	$555,676	$19,702	$600,000	$0	$0	$231,309

ASSUMPTIONS:

ALL COSTS IN CONSTANT 1984 DOLLARS
(ASSUMING 1.39 INFL BETWEEN 1980-1984)
(A 1.15 "DIFFERENTIAL INFL FACTOR" WAS ASSUMED
FOR HEALTH CARE COSTS BY HHS)

ANNUAL EARNINGS: (AGES 18 TO 65)	$18,200
DISCOUNT RATE:	2.50%
ATT. FEES (% OF SUBTOTAL):	20.00%
TOTAL COST FOR SHORT HOSPITALIZATION:	$2,500
INCIDENCE (CASES IN 1984):	2865
-SHORT HOSPITALIZATION	2700
-ACUTE CATEGORY	114
-CHRONIC CATEGORY	47
-DEATH CATEGORY	4

	ANNUAL	% CLAIM	TOTAL
RETROACTIVE INCIDENCE (PRE 1984):	212		650
-ACUTE CATEGORY	147	0%	0
-CHRONIC CATEGORY	61	50%	610
-DEATH CATEGORY	4	50%	40

NUMBER OF YEARS FOR RETROACTIVE CASES:	20
LIFE EXPECTANCY (YEARS):	73

NATIONAL CHILDHOOD VACCINE INJURY COMPENSATION ACT

Annual Cash Flow

Base Case
73 Year Life

YEAR	ACTUAL	LUMP SUM	TEN YEAR
1	$85,623,500	$230,900,474	$205,360,446
2	$85,694,094	$230,900,474	$205,360,446
3	$30,958,609	$44,915,991	$19,375,963
4	$31,029,203	$44,915,991	$19,375,963
5	$31,099,797	$44,915,991	$19,375,963
6	$31,170,391	$44,915,991	$19,375,963
7	$31,240,985	$44,915,991	$19,375,963
8	$31,311,579	$44,915,991	$19,375,963
9	$31,382,173	$44,915,991	$19,375,963
10	$31,452,767	$44,915,991	$44,915,991
11	$31,523,361	$44,915,991	$44,915,991
12	$31,593,955	$44,915,991	$44,915,991
13	$31,664,549	$44,915,991	$44,915,991
14	$31,735,143	$44,915,991	$44,915,991
15	$31,805,737	$44,915,991	$44,915,991
16	$31,876,331	$44,915,991	$44,915,991
17	$31,946,925	$44,915,991	$44,915,991
18	$32,088,113	$44,915,991	$44,915,991
19	$33,014,107	$44,915,991	$44,915,991
20	$33,940,101	$44,915,991	$44,915,991
21	$34,866,095	$44,915,991	$44,915,991
22	$35,792,089	$44,915,991	$44,915,991
23	$36,718,083	$44,915,991	$44,915,991
24	$37,644,077	$44,915,791	$44,915,991
25	$38,570,071	$44,915,991	$44,915,991
26	$39,496,065	$44,915,991	$44,915,991
27	$40,422,059	$44,915,991	$44,915,991
28	$41,348,053	$44,915,991	$44,915,991
29	$42,274,047	$44,915,991	$44,915,991
30	$43,200,041	$44,915,991	$44,915,991
31	$44,126,035	$44,915,991	$44,915,991
32	$45,052,029	$44,915,991	$44,915,991
33	$45,978,023	$44,915,991	$44,915,991
34	$46,904,017	$44,915,991	$44,915,991
35	$47,830,011	$44,915,991	$44,915,991
36	$48,756,005	$44,915,991	$44,915,991
37	$49,681,999	$44,915,991	$44,915,991
38	$50,607,993	$44,915,991	$44,915,991
39	$51,533,987	$44,915,991	$44,915,991
40	$52,459,981	$44,915,991	$44,915,991
41	$53,385,975	$44,915,991	$44,915,991
42	$54,311,969	$44,915,991	$44,915,991
43	$55,237,963	$44,915,991	$44,915,991
44	$56,163,957	$44,915,991	$44,915,991
45	$57,089,951	$44,915,991	$44,915,991
46	$58,015,945	$44,915,991	$44,915,991
47	$58,941,939	$44,915,991	$44,915,991
48	$59,867,933	$44,915,991	$44,915,991
49	$60,793,927	$44,915,991	$44,915,991

Annual Cash Flow
(continued)

Base Case
73 Year Life

50	$61,719,921	$44,915,991	$44,915,991
51	$62,645,915	$44,915,991	$44,915,991
52	$63,571,909	$44,915,991	$44,915,991
53	$64,497,903	$44,915,991	$44,915,991
54	$65,423,897	$44,915,991	$44,915,991
55	$66,349,891	$44,915,991	$44,915,991
56	$67,275,885	$44,915,991	$44,915,991
57	$68,201,879	$44,915,991	$44,915,991
58	$69,127,873	$44,915,991	$44,915,991
59	$70,053,867	$44,915,991	$44,915,991
60	$70,979,861	$44,915,991	$44,915,991
61	$71,905,855	$44,915,991	$44,915,991
62	$72,831,849	$44,915,991	$44,915,991
63	$73,757,843	$44,915,991	$44,915,991
64	$62,665,617	$44,915,991	$44,915,991
65	$63,591,611	$44,915,991	$44,915,991
66	$63,662,205	$44,915,991	$44,915,991
67	$63,732,799	$44,915,991	$44,915,991
68	$63,803,393	$44,915,991	$44,915,991
69	$63,873,987	$44,915,991	$44,915,991
70	$63,944,581	$44,915,991	$44,915,991
71	$64,015,175	$44,915,991	$44,915,991
72	$64,085,769	$44,915,991	$44,915,991
73	$64,156,363	$44,915,991	$44,915,991
74	$64,156,363	$44,915,991	$44,915,991
75	$64,156,363	$44,915,991	$44,915,991
76	$64,156,363	$44,915,991	$44,915,991
77	$64,156,363	$44,915,991	$44,915,991
78	$64,156,363	$44,915,991	$44,915,991
79	$64,156,363	$44,915,991	$44,915,991
80	$64,156,363	$44,915,991	$44,915,991

NATIONAL CHILDHOOD VACCINE INJURY COMPENSATION ACT

Cost Per Case

COST CATEGORY	ACUTE YEAR 1	ACUTE FUTURE PV	ACUTE ANN.	CHRONIC YEAR 1	CHRONIC FUTURE PV	CHRONIC ANN.	DEATH YEAR 1	DEATH FUTURE PV	DEATH ANN.	WEIGHTED AVERAGE NPV/CASE
MEDICAL COSTS										
-Hospital care	$3,004			$10,515						$5,071
-Inpatient specialist	$192			$563						$293
-Inpatient non-spec.	$177			$531						$274
-Outpatient specialist	$26			$53						$33
-Outpatient non-spec.	$58			$156	$771	$31				$304
REHABILITATION COSTS										
-Home modification				$5,560						$1,584
-Physical therapy				$1,567						$446
-Occupational therapy				$992						$283
-Special education					$26,698	$1,063				$7,605
-Long-term care					$10,313	$730				$5,216
-Equipment				$895	$4,423	$176				$1,515
TOTAL MED. & REHAB. COSTS	$3,457	$0	$0	$20,832	$50,205	$2,000	$0	$0	$0	$22,623
LOST EARNINGS					$315,444	$18,200				$89,854
PAIN & SUFFERING	$10,000			$25,000						$14,030
SURVIVOR BENEFITS							$500,000			$12,121
SUBTOTAL	$13,457	$0	$0	$45,832	$365,649	$20,200	$500,000	$0	$0	$138,629
ATTORNEY FEES	$2,691			$82,296			$100,000			$27,726
TOTAL	$16,148	$0	$0	$128,126	$365,649	$20,200	$600,000	$0	$0	$166,354

ASSUMPTIONS:

ALL COSTS IN CONSTANT 1984 DOLLARS
(ASSUMING 1.39 INFL BETWEEN 1980-1984)
(A 1.15 "DIFFERENTIAL INFL FACTOR" WAS ASSUMED FOR HEALTH CARE COSTS BY HHS)

ANNUAL EARNINGS: (AGES 18 TO 65) $18,200

DISCOUNT RATE: 2.50%

ATT. FEES (% OF SUBTOTAL): 20.00%

TOTAL COST FOR SHORT HOSPITALIZATION: $2,500

INCIDENCE (CASES IN 1984): 2865
-SHORT HOSPITALIZATION 2700
-ACUTE CATEGORY 114
-CHRONIC CATEGORY 47
-DEATH CATEGORY 4

	ANNUAL	% CLAIM	TOTAL
RETROACTIVE INCIDENCE (PRE 1984):	212		650
-ACUTE CATEGORY	147	0%	0
-CHRONIC CATEGORY	61	50%	610
-DEATH CATEGORY	4	50%	40

NUMBER OF YEARS FOR RETROACTIVE CASES: 20

LIFE EXPECTANCY (YEARS): 40

NATIONAL CHILDHOOD VACCINE INJURY COMPENSATION ACT

Sensitivity Run
40 Year Life

Annual Cash
Flow

YEAR	ACTUAL	LUMP SUM	TEN YEAR
1	$77,024,526	$165,850,699	$149,433,169
2	$77,118,526	$165,850,699	$149,433,169
3	$29,522,947	$34,198,469	$17,780,940
4	$29,616,947	$34,198,469	$17,780,940
5	$29,710,947	$34,198,469	$17,780,940
6	$29,804,947	$34,198,469	$17,780,940
7	$29,898,947	$34,198,469	$17,780,940
8	$29,992,947	$34,198,469	$17,780,940
9	$30,086,947	$34,198,469	$17,780,940
10	$30,180,947	$34,198,469	$34,198,469
11	$30,274,947	$34,198,469	$34,198,469
12	$30,368,947	$34,198,469	$34,198,469
13	$30,462,947	$34,198,469	$34,198,469
14	$30,556,947	$34,198,469	$34,198,469
15	$30,650,947	$34,198,469	$34,198,469
16	$30,744,947	$34,198,469	$34,198,469
17	$30,838,947	$34,198,469	$34,198,469
18	$31,026,947	$34,198,469	$34,198,469
19	$31,976,347	$34,198,469	$34,198,469
20	$32,925,747	$34,198,469	$34,198,469
21	$33,875,147	$34,198,469	$34,198,469
22	$34,824,547	$34,198,469	$34,198,469
23	$35,773,947	$34,198,469	$34,198,469
24	$36,723,347	$34,198,469	$34,198,469
25	$37,672,747	$34,198,469	$34,198,469
26	$38,622,147	$34,198,469	$34,198,469
27	$39,571,547	$34,198,469	$34,198,469
28	$40,520,947	$34,198,469	$34,198,469
29	$41,470,347	$34,198,469	$34,198,469
30	$42,419,747	$34,198,469	$34,198,469
31	$43,369,147	$34,198,469	$34,198,469
32	$44,318,547	$34,198,469	$34,198,469
33	$45,267,947	$34,198,469	$34,198,469
34	$46,217,347	$34,198,469	$34,198,469
35	$47,166,747	$34,198,469	$34,198,469
36	$48,116,147	$34,198,469	$34,198,469
37	$49,065,547	$34,198,469	$34,198,469
38	$50,014,947	$34,198,469	$34,198,469
39	$50,964,347	$34,198,469	$34,198,469
40	$51,913,747	$34,198,469	$34,198,469
41	$39,591,747	$34,198,469	$34,198,469
42	$39,591,747	$34,198,469	$34,198,469
43	$39,591,747	$34,198,469	$34,198,469
44	$39,591,747	$34,198,469	$34,198,469
45	$39,591,747	$34,198,469	$34,198,469
46	$39,591,747	$34,198,469	$34,198,469
47	$39,591,747	$34,198,469	$34,198,469
48	$39,591,747	$34,198,469	$34,198,469
49	$39,591,747	$34,198,469	$34,198,469

Annual Cash Flow

(Continued)

Sensitivity Run
40 Year Life

50	$39,591,747	$34,198,469	$34,198,469
51	$39,591,747	$34,198,469	$34,198,469
52	$39,591,747	$34,198,469	$34,198,469
53	$39,591,747	$34,198,469	$34,198,469
54	$39,591,747	$34,198,469	$34,198,469
55	$39,591,747	$34,198,469	$34,198,469
56	$39,591,747	$34,198,469	$34,198,469
57	$39,591,747	$34,198,469	$34,198,469
58	$39,591,747	$34,198,469	$34,198,469
59	$39,591,747	$34,198,469	$34,198,469
60	$39,591,747	$34,198,469	$34,198,469
61	$39,591,747	$34,198,469	$34,198,469
62	$39,591,747	$34,198,469	$34,198,469
63	$39,591,747	$34,198,469	$34,198,469
64	$39,591,747	$34,198,469	$34,198,469
65	$39,591,747	$34,198,469	$34,198,469
66	$39,591,747	$34,198,469	$34,198,469
67	$39,591,747	$34,198,469	$34,198,469
68	$39,591,747	$34,198,469	$34,198,469
69	$39,591,747	$34,198,469	$34,198,469
70	$39,591,747	$34,198,469	$34,198,469
71	$39,591,747	$34,198,469	$34,198,469
72	$39,591,747	$34,198,469	$34,198,469
73	$39,591,747	$34,198,469	$34,198,469
74	$39,591,747	$34,198,469	$34,198,469
75	$39,591,747	$34,198,469	$34,198,469
76	$39,591,747	$34,198,469	$34,198,469
77	$39,591,747	$34,198,469	$34,198,469
78	$39,591,747	$34,198,469	$34,198,469
79	$39,591,747	$34,198,469	$34,198,469
80	$39,591,747	$34,198,469	$34,198,469

This appendix contains two resource utilization profiles from Appendix C, Estimated Economic Costs of Selected Medical Events Known or Suspected to be Related to the Administration of Common Vaccines, Department of Health, Education and Welfare, Public Health Service, Office of the Assistant Secretary for Health, National Center for Health Services Research, December 31, 1979. These profiles represent the Acute and Chronic categories in PHB's analysis and were used to estimate costs.

REPRESENTS ACUTE ILLNESS CATEGORY

3. Moderate Encephalitis, Encephalomyelitis, and Aseptic Meningitis due to DTP Vaccine characterized by Collapse and resulting in Complete Recovery.

Patient Scenario: Patient experiences Mild Encephalitis characterized by decreased spontaneous activity, poor fluid intake, marked lethargy and pallor lasting 7 days and resulting in complete recovery. (Patient age is 6 weeks to 6 years.)

Degree of Impairment: 100% for 7 days.

Acute Inpatient Utilization:

- Length of stay: 7 days. (Estimate based on severity of disease. Mean length of stay is 8.8 days with a Standard Deviation of 12.1, a range of 81.0 and a Median of 5.0 days for Other Encephalitis, Viral.)*
- 3 consults with Neurologist.
- 1 consult with Infectious Disease Specialist
- Attending physician visits daily: Pediatrician
- Special Procedures:
  - Lumbar Puncture
  - Serial Electroencephalograms
- Physical Therapy/Occupational Therapy
  - Physical therapy daily for exercise
  - Occupational therapy daily for diversional benefit

Outpatient Utilization:

- 2 consults with Neurologist
- 4 office visits to Pediatrician

Chronic Inpatient Utilization: None

*REPRESENTS CHRONIC ILLNESS CATEGORY

7. Severe Encephalitis, and Encephalomyelitis due to DTP Vaccine resulting in Psychomotor Retardation.

Patient Scenario: Patient experiences Severe Encephalitis/Encephalomyelitis characterized by fever, convulsions, hypotonia, hemiplegia and meningeal signs resulting in psychomotor retardation. (Patient age is 6 weeks to 6 years.)

Degree of Impairment: 75%

(Estimate based on category of Mental Deterioration, Severe, which is rated 75% in the Labor Code of the State of California.)

Acute Inpatient Utilization:

- Length of stay: 3 weeks. (Estimate is based on severity of disease. Average length of stay for Other Encephalitis, Viral, is 8.8 days with a Standard Deviation of 12.1 and a Range of 81.0. The Median is 5.0 days.)*
- 5 consults with Neurologist.
- 2 consults with Infectious Disease Specialist.
- Attending physician visits daily: Pediatrician.
- Intensive nursing care for 1 week, then routine care for 2 weeks.
- Special Procedures:
  - Lumbar Puncture
  - Serial Electroencephalograms
  - Blood anticonvulsant level determination
- Drug Therapy:
  - Phenobarbitol
- Physical Therapy/Occupational Therapy:
  - Physical Therapy daily for 2 weeks for family instruction, gait training and exercise.
  - Occupational Therapy daily for 2 weeks for self care and diversional benefits.
  - Developmental assessment by multidisciplinary team including Physical Medicine Specialist, Psychologist, Neurologist and Physical Therapist.

Outpatient Utilization:

- Consults with a Neurologist every 6 months for 1 year.
- Physician office visits to a Pediatrician 4 times per year until age 18, then visits to Primary Care Specialist annually for life.
- Physical Therapy/Occupational Therapy:
    - Physical Therapy weekly for 1 year for exercise and gait training.
    - Speech Therapy 1 time per week for 2 years.
    - Occupational Therapy 1 time per week for 1 year for self-care activities.
- Special Equipment:
    - Long leg brace
    - Crutches
    - Wheelchair
    - Rolling Walker
- Special schooling for 12 years.

Chronic Inpatient Utilization:

- Domiciliary care from age 15 for life.
- Vocational training and sheltered workshop for 1 year.

This appendix contains summary tables and graphs of the estimated costs of the bill if the average life of patients in the Chronic Category is 40 years instead of 73 years. Exhibit C.1 tabulates the cost per case by disease category. These costs can be compared to those for a 73 year life in Exhibit 4 in the text. If patients actually live an average of 40 years, the net present value cost of compensation for chronic patients is $494,000, about two-thirds of the base case costs. Exhibit C.2 shows the cost components per case.

As Exhibit C.3 shows, costs over time would also be lower and the difference between steady state costs in the three options would be smaller. Steady state costs are more similar because the costs for mild, acute and death cases which are common among all options, are a larger proportion of total annual cost. This graph can be compared to Exhibit 6 in the text for a 73 year life expectancy.

Exhibit C.1

COSTS PER CASE BY ILLNESS CATEGORY (40 YEAR LIFE)
(Constant 1984 dollars)

	ACUTE			CHRONIC			DEATH			
Cost Category	Year 1	Annual	NPV	Year 1	Annual*	NPV	Year 1	Annual	NPV	Weighted Avg NPV
Medical Expenses	$ 3,457	$ 0	$ 3,457	$ 11,818	$ 31	$ 12,589	$ 0	0	$ 0	$ 5,975
Rehabilitation, etc.	0	0	0	9,014	1,969	58,448	0	0	0	16,648
Pain and Suffering	10,000	0	10,000	25,000	0	25,000	0	0	0	14,030
Earnings Loss	0	0	0	0	18,200**	315,444	0	0	0	89,854
Survivor Benefits	0	0	0	0	0	0	500,000	0	500,000	12,121
Legal Fees	2,691	0	2,691	82,296	0	120,302	100,000	0	100,000	38,552
Total	$16,148	$ 0	$16,148	$128,128	$20,200	$493,777	$600,000	$ 0	$600,000	$166,354

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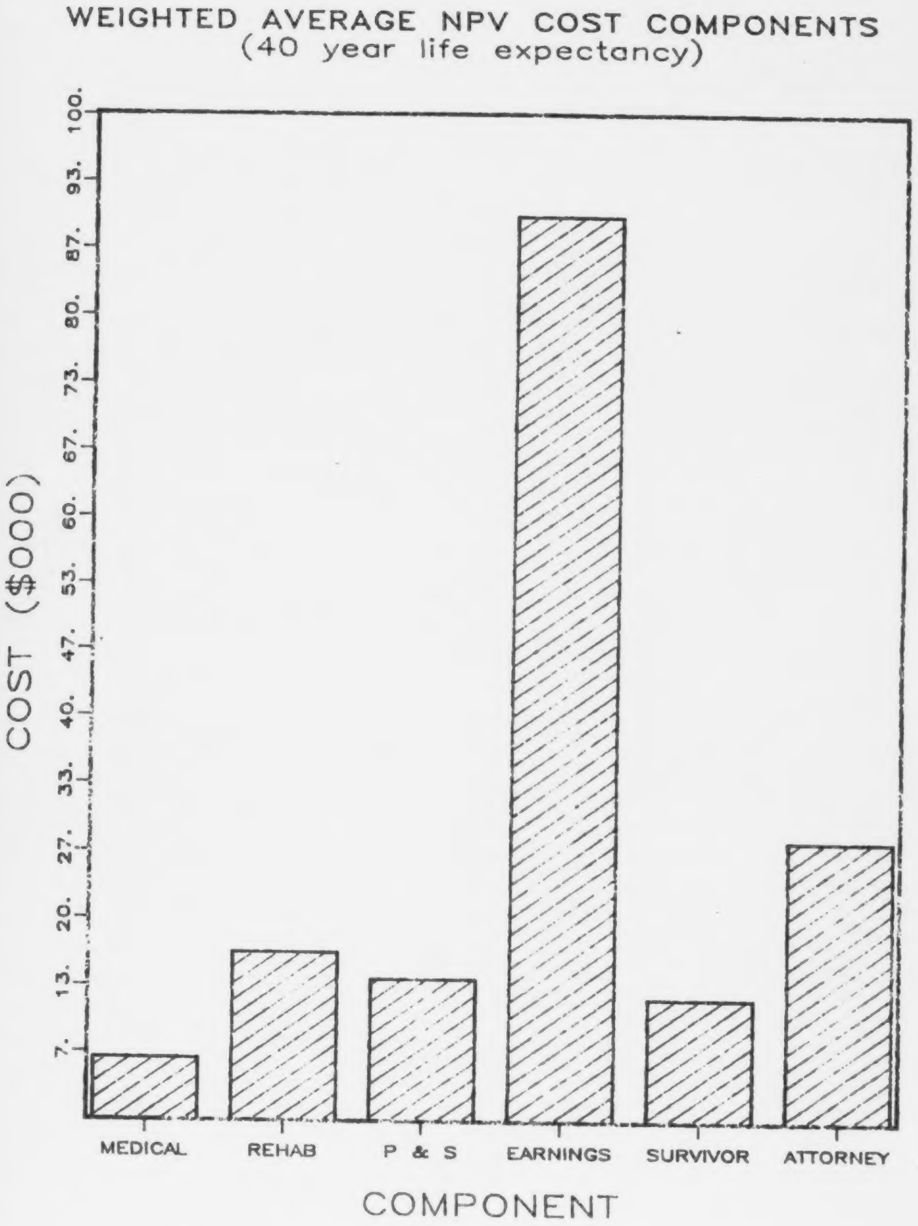
* Calculated by annualizing the NCHSR's present value of costs excluding year 1. A 73-year life was assumed.

** Compensation for lost earnings does not begin until the 18th year and lasts until the claimant dies at 40.

Exhibit C.2

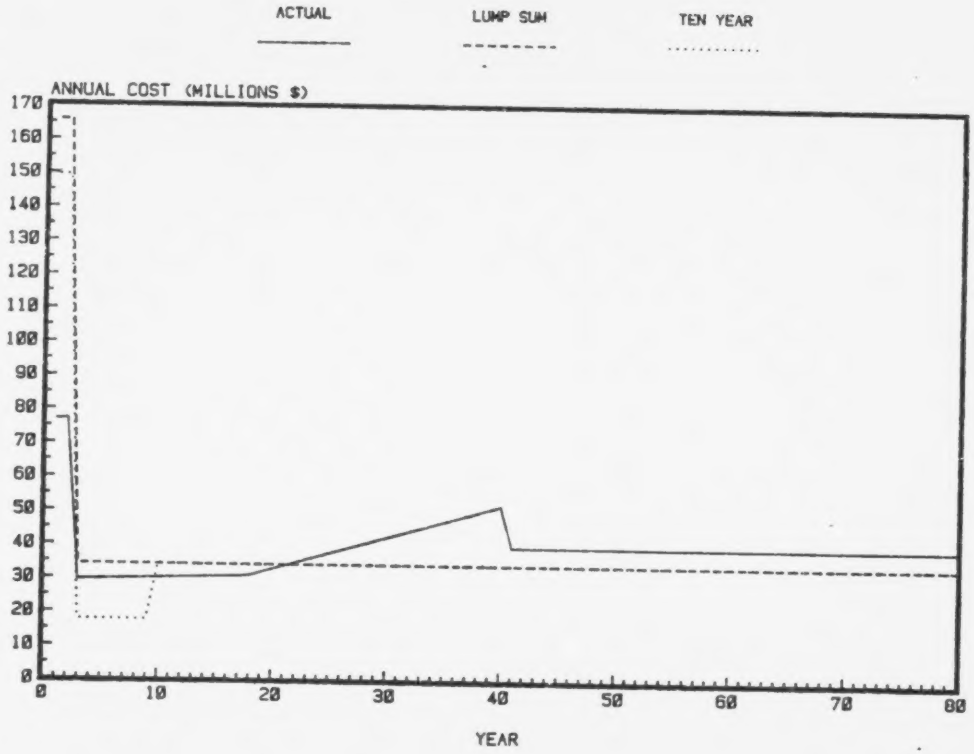


WEIGHTED AVERAGE NPV COST COMPONENTS
(40 year life expectancy)

EXHIBIT C.5

PAYMENT SCHEDULE

40 YEAR LIFE EXPECTANCY



Senator HAWKINS. I believe you said that your study shows the cost would be about one quarter or maybe even less than that, because CBO's figures are costed on 100 percent of every case?

Dr. SMITH. We are not sure how CBO's figures were developed. We have no information of the details of their development.

Ours are based on 100 percent of the cases being covered by the system. Nevertheless, there is a tremendous difference in the cost estimate. Ours runs really less than one-fourth.

We estimate that in the first 2 years the program can be adminstered for about $150 million. After the first 2 years, that you reach a steady state of annual cost of approximately $50 million.

These figures can be changed to some extent up or down depending on the variables that exist in the entire program—such things as how the payment options are designed, whether or not they are settled in a lump sum fashion or whether it is spaced over the years. It depends on the life span, the best estimate that you can arrive at of the life span of a seriously injured individual. The estimate bases the cost for that seriously injured individual at 73 years, a full, normal life span. We doubt that this occurs. We think it is more likely on the order of 40 years.

It depends on the number of cases grandfathered in at the outset of the program, and it depends, further, of course, on the number of people who finally choose the compensation system. All of these are variables that can determine a great deal of the differences in cost.

Senator HAWKINS. We appreciate your working with us on the bill, Dr. Smith. It is my understanding that when we received a copy of your estimate of the cost from your experts and provided it to CBO, CBO wanted to go back to the drawing board and look again at their costs. Hopefully, your study will lower those costs.

Do you feel it is necessary to provide a table of injuries in the bill?

Dr. SMITH. We feel that, in one way or another, one place or another, there has to be finally and ultimately a table of injuries.

One of the concerns that we have always had expressed about this concept from the beginning has been the numbers of instances that could be classed as temporally associated events—events that they might occur around the time of an immunization and they might not be possible to distinguish from a reaction to the immunization either clinically or pathologically.

This table of events, the table of injuries, with associated times connected with them, is an effort to sift out those instances or temporally associated events, as many as possible. It will not be perfect, but it will sift out the majority of the temporally associated events.

The advantage of incorporating it into the legislation is that it does put it in place immediately and allows the program to start sooner, rather than going through the process of rulemaking, regulation formation, and so on, which would take a couple of years.

We feel that there is some advantage in having it in the legislation. There is incorporated in the legislation opportunity for alterations of the table with additional time and experience.

Senator HAWKINS. Are you concerned with the supply of vaccine?

Dr. **Smith.** Terribly concerned. That has been one of our greatest concerns from the very beginning, as we have seen the number of vaccine producers shrink and, of course, as we have seen the costs more recently escalate.

I have heard various descriptions of the stockpile. One that I have heard has been 6 weeks. Now that is not a very adequate safeguard for our supply if someone suddenly decides to leave the marketplace.

Senator **Hawkins.** Thank you so much, Dr. Smith.

Dr. King, we appreciate your joining us today. I know the Florida Legislature is in session, considering a number of important health bills, and that you should be there to help them.

Dr. **King.** That is correct.

Senator **Hawkins.** I appreciate your taking the time.

You mentioned ASTHO's concern about the cost of the bill and its relationship to a State's ability to purchase vaccines for distribution among its public health clinics.

Dr. **King.** That is correct. I think that one of the difficulties for the States, those folks in the public health agencies in the States, in dealing with this issue is to sort out what we are trying to do with the bill and the impact that is going to have on the day-to-day administration of the program. I think that is where a lot of the concern that you hear is coming from.

Inevitably, what we are trying to do here today is going to mean that the immunization program in this country is going to be much more expensive. We have heard dollars and, even within the margin of error of the dollars that you are talking about, you are talking about a great expense. It will not be just a Federal expense, a U.S. expense; it will be a State expense, too.

Even without that, the cost of vaccines is rising so rapidly that both those that we purchase through the centers and those that we purchase through our own State purchasing contracts are getting quite a bit higher.

If I am not mistaken, I appeared before you on a committee hearing last fall in which we discussed the same issue then, and it is a very real problem and we are all quite concerned about it.

The cost of the administration of the program I think is something that can be dealt with, and I think that is something the administration people who are in the administration can concern themselves about with any new idea.

However, one of the things which has been barely touched on, which is critically important to this bill and to what it is trying to do, is the information it generates. The real progress is made in the elimination of the disease in our society with technically valid information. It has happened throughout the years, and it continues to be the case now.

We do not have—at least in our State--the kind of information that we would like to have that tells us really what do we have out there in the way of vaccine-related injuries. We have some idea in some sectors. Some counties are better than others in reporting. The private medical community is improving daily. However, if you were to ask me today exactly how many vaccine-related injuries have there been and will there be in the State of Florida, I could not tell you that, and I need to know that. I need to know that, and

I think every State health office in the country needs to know. I think the Center desperately needs to know that. We are working very hard on getting in that direction now. We are improving daily.

That is why when the two concepts come together—the concept and need for compensation, which is real; we have a societal obligation—on the other hand, what is the nature of the problem really? It is hard to know how big the problem is, exactly what the relationship is to what we are doing on a day-to-day basis. Hopefully, we can help iron that out.

Senator HAWKINS. Florida is a gateway State because of our geographic location.

Dr. KING. That is correct.

Senator HAWKINS. We are the entry point for refugees, immigrants, visitors from nations——

Dr. KING. And college students from the North, too. [Laughter.]

Senator HAWKINS. I was getting to that. [Laughter.]

And from other countries that do not have active immunization programs.

Dr. KING. That is correct.

Senator HAWKINS. Does this make Florida at risk of epidemics?

Dr. KING. Yes, Madam Chairman, it does.

We had in 1983, although our total numbers of cases for the year were down from the year before, we still had far too many cases in the State, and they were almost all, as far as I can tell, directly related to the importation from South America and the rest of the world of a new case of measles. It proved particularly difficult because the population at risk at that point in time, at greatest risk, was the middle school population, although we did have some secondary spread to the younger children. We are constantly on our guard, and we have had a number of counties which have had to go through a fairly major school exclusion process in which every child in a school or in an entire school system, if it is already into the secondary generation of cases and spread beyond the first schools, had to be removed from school for a period of several days to a couple of weeks to get the immunization status up to the point that we can afford to let the children back in to keep the spread of the disease down. That continues to be a very real problem.

The encouraging thing, I believe, however, is that measles is one of these diseases like smallpox in which the only reservoir, as far as we know, is the human reservoir and potentially it is eradicable.

I think it is so important at this point in time that we do not hesitate on the brink of our success. I think within our lifetimes we may well see what we have seen with smallpox, and what we need to do is to push ahead if we can.

But, yes, we do have a problem in Florida because of that.

Senator HAWKINS. Is the Florida Legislature proposing any mandatory reporting for reaction to pertussis?

Dr. KING. No, I am not aware of any legislation in the State senate or the house at the present time for reporting. We have begun an effort, however, as a part of our program to improve our reporting. We are in the process of doing that right now.

Senator HAWKINS. How about mandating the dissemination of information to the parents of adverse reactions, possible adverse reactions, prior to the first shot?

Dr. KING. We have begun a very extensive process, which is mostly in the planning stages right now, of doing that administratively. I am not aware of a specific bill in the Florida Legislature at this point on that issue.

Senator HAWKINS. Can States do it administratively without legislation?

Dr. KING. Yes. Oh, yes, and we intend to.

Senator HAWKINS. Do you know how many States have done this?

Dr. KING. No, I am not aware. I am sorry.

Senator HAWKINS. We appreciate your cooperation. We look forward to working with you on this legislation as it develops.

Dr. Nelson, AMA, one of the proposals that you considered was to convene an expert panel that would define the clinical parameters for identifying vaccine-related injuries and the projected care, needs, of the injured individual. How do you view the use of such an expert panel?

Dr. NELSON. This was also one of the recommendations in the report of the National Immunization Work Group that was commissioned by HEW in 1977. We felt that, given the alternatives for defining eligibility and compensable events, having an expert panel convened and identify the compensable events for proposed rulemaking was a more desirable alternative than to have some listing of adverse reactions and eligibility criteria as part of the bill itself.

I think it should not be difficult for the Secretary to identify a group of experts that are recognized nationally in their field and use them as a resource in developing proposed rules.

Senator HAWKINS. The Department of HHS has a very strong position regarding immunizations, however. I understand the Secretary has termed failure to immunize a child a form of child abuse. In your mind, doesn't that impose a conflict of interest for the Secretary to say that if a child is not immunized, that is child abuse and at the same time having to be involved in the appointment of a panel and also be involved in compensation?

Dr. NELSON. Well, I think you would have to ask the Secretary whether that represented some inconsistency. I have confidence in the ability of the Secretary to carry out the mandates of a bill that would call for him convening a special panel to assist in defining eligibility.

Senator HAWKINS. Should the Secretary be involved in determining eligibility compensation?

Dr. NELSON. I suppose that he would insofar as——

Senator HAWKINS. It is a "she" right now.

Dr. NELSON. Pardon me, he or she would insofar as being responsible for the publication of the proposed rules.

Senator HAWKINS. Thank you.

Dr. Salk, it is a pleasure to have you with us. Your work has earned you justifiable renown and saved countless lives. I remember as a young girl the panic of the polio epidemic—closed swimming pools, closed theaters, and the fear we lived in, especially in the South. I can remember the relief, also, when a vaccine for polio was developed.

Your testimony poses a very interesting question. How can we structure a compensation program which encourages the use of the safest of all available vaccines?

Dr. SALK. I think it is a matter of incentive and it is a matter of penalty. The question is, Who is to provide the incentive and who is to provide the penalty? In the case of vaccine-associated injuries, it is clear that it would be far more desirable to avoid them, far more desirable to have vaccines that do not require the use of compensation as remedy. In the event that compensation is necessary, it seems to me that the kind of legislation that you are proposing would be desirable. A careful distinction must be made between those instances in which there is no other remedy and those in which there is.

It seems to me that in this instance, where alternative vaccines exist as is the case of poliovirus vaccine, that the indemnification for such damages should not be included in the bill inasmuch as the evidence is now clear that there is a polio vaccine that can be administered effectively without inducing injury, and there is one that does induce injury in a small number of instances. My suggestion would be that for instances in which there is no such an alternative that indemnification measures are required. However, where a safe alternative exists then indemnification as a solution should not be available.

Senator HAWKINS. Do you think the Federal Government needs to take a larger role in vaccine development, production, and usage?

Dr. SALK. Yes; I do. I think that this is a major and important public health measure. With more attention in this regard on the part of Government authorities, encouragement for the necessary research would be available. This would be true, as has already been mentioned, not only in improving vaccines that already exist to make them risk free, but also in making vaccines available for diseases that still are prevalent and for which preventatives are clearly required.

Senator HAWKINS. As you reflect back on your successes, did it take the polio epidemic of the fifties to bring about the solution?

Dr. SALK. No. Research on polio had been going on for quite some time.

Senator HAWKINS. How long?

Dr. SALK. You may recall that Franklin Roosevelt had been paralyzed. During his Presidency, in the year 1938, the organization called the March of Dimes was created. About a decade later it became possible to say that polio was caused by three viruses. The polio virus could be produced in tissue culture, and soon thereafter it was possible to develop a vaccine. Polio, as an epidemic disease, had been mounting steadily for several decades. It is fortunate that a vaccine did become available when it did or else cases would have continued to accumulate in excess of the average of 25,000 cases of polio annually.

Senator HAWKINS. Thank you, Dr. Salk.

Mr. Dodd, is it just as difficult to ascertain the identification of the manufacturer of a vaccine administered by a private pediatrician as a vaccine administered by a public clinic, in your opinion?

Mr. DODD. There seems to be a dispute in the profession about that issue. In California, I think we are generally blessed with a very high level of care, of health-care providers. It has not been the experience throughout the country that that standard is necessarily even with regard to pertussis immunization, which is what I am familiar with.

It appears that in some areas of the country there is a failure generally to follow medical contraindications. So, the exposure of a physician in these kinds of lawsuits seems to vary a lot. There is no common feeling about what that exposure is. My personal feeling is the exposure in the situation that I am familiar with is small. However, on the other hand, that may not be the experience in other parts of the country. That is a very difficult question to answer.

Senator HAWKINS. Will the provision of the compensation option effectively allow negligent vaccine manufacturers and doctors to avoid liability?

Mr. DODD. Well, that depends on two things. Obviously, if the bill were mandatory, there would be that risk. As the bill presently stands, there is authority, as I understand it, for the Government to pursue those individuals who the Government determines may be culpable in some sense. Depending on how that was actually implemented, which I do not think is something that one could write every step into the bill—it would not be possible— depending on the manner in which the bill is implemented, that may or may not be true. If the Government was vigorous, if the Government was examining records, if the Government was out there really trying to determine culpability, I do not think it would permit the manufacturer or health care provider who might be involved to escape.

Senator HAWKINS. In your opinion, is the Government vigorous in enforcing the vaccination?

Mr. DODD. Enforcing the——

Senator HAWKINS. Of children before they go to school?

Mr. DODD. Quite, yes. The Government is quite vigorous. We have heard from one gentleman about Arkansas, which I am not familiar with.

All levels of government that I am aware of, all the way down to the county health officials, are extremely vigorous in implementing this policy because they know in general that immunization in this country has been an enormous boon to this society, but they paint everything with a very broad brush, and it is very difficult for them to recognize where there may be problems in our immunization policy, where immunization with certain products may be based on faulty assumptions or false epidemiological studies, false assumptions about the vaccine. However, generally, the people who implement this program from all levels are committed to immunization, and for good reason in general.

Senator HAWKINS. You heard Dr. King speak of the resolution they passed in 1974.

Dr. KING. I'm sorry; 1978.

Senator HAWKINS. In 1978. Obviously, it was of concern to the State health officials back in 1978. In your experience as an attorney, why do you feel that the same officials that are concerned don't show the same interest in reporting adverse reactions?

Mr. DODD. Senator Hawkins, it has been stated by several experts who routinely appear for the defense in lawsuits involving pertussis immunization that it has been known in our society for a long time that reactions are notoriously underreported. Why that might be? It is very difficult to say. It may be that there is inadequate information disseminated by the Federal Government, the local government, and the manufacturer, specifically again related to DPT, which is what I am familiar with, as to what to watch for. It may be that physicians assume that all vaccines have the same relative level of risk, and it may be that physicians assume that injury with regard, for instance, to pertussis immunization is very rare, is very idiosyncratic, as is generally true with other vaccines.

Dr. Salk has talked about the rate of injury with regard to the polio vaccine. That is a relatively small number.

It is the opinion of many experts that the risk related to pertussis immunization is not in the same ball park with these other vaccines; that there is an order of magnitude that is incredibly multiplied with pertussis immunization.

Again, physicians familiar with the polio vaccines, with the other modern vaccines that we have, know in their hearts that there are possible reactions—maybe one or two. The common wisdom goes that you can have a reaction to aspirin, and there have been such things reported, but these are rare; these are very rare events.

Pertussis immunization, we feel, presents a wholly different picture. Of course, again, we are certainly not talking about thousands of children a year. If we were, I don't think there would be anybody here to oppose the bill, Senator Hawkins, but we are talking about a significant number of children and we are talking about young attorneys in my position who are now losing clients to death. Now that is a unique experience for me. I am not old enough to have a lot of clients with wills and trusts who, so the saying goes, the wills and trusts mature; the people die. But now, I am losing young clients, and these are existing clients, and these are clients who did not come to me in time for me to help them.

As I have stated in my written testimony, right now attorneys are the last resort for these children. These children all present massive medical records—300 or 400 pages long. They have been to the Mayo Clinic. They have been to every clinic that has a pediatric neurologist. Again, there is only so much that any physician can do with the kind of seizure disorder that these children are frequently presented with. There is only a limited amount one can do.

It is unfortunately true that in order to improve the quality of life of these kids as best we can, it takes a great deal of money. It takes a great deal of professional assistance from physicians. It takes therapists. It takes paraprofessionals. There are all kinds of different things that can be done, but they are expensive.

Senator HAWKINS. But it is also expensive not to do?

Mr. DODD. I think the secret, really, to the response to the people in regard to this bill who suggest it is going to be very expensive is—and I think this has been mentioned by several physicians on this panel—these children have a built-in, fixed cost, anyway. They are getting supplemental social security disability. They are getting aid from private charities. They may be getting State aid.

What middle class family in this country can afford the actuarily projected expense to take care of one of these children? I don't know of any.

These children have a fixed cost that our society is paying. What we are talking about in this bill, I think, is focusing the cost into one central area, but I don't see that we are increasing the cost. I cannot accept that.

Senator HAWKINS. Thank you all very much for appearing with us today and helping to resolve this very significant problem for children and parents.

Now we would like to call our final panel, representatives of very brave U.S. vaccine manufacturers: the Michigan Department of Public Health and Biologics, one of the two States involved in the production of vaccine, which was quite a surprise to me—that States are now involved in production rather than chemical manufacturers, and they will be represented by Kenneth Eaton and Vince Leone, who is assistant attorney general for the State of Michigan.

We also are privileged to have Mr. John Lyons, who is president of Merck Sharpe & Dohme, who is the sole producer of the vaccine for MMR—measles, mumps, and rubella. He will be here accompanied by counsel.

In addition, we would like to say that Wyeth Laboratories and Lederle Laboratories have submitted testimony for the record.

[The prepared statements of Wyeth and Lederle Laboratories follow:]

WYETH LABORATORIES Wyeth *P. O. Box 8299, Philadelphia, Pennsylvania 19101*

RICHARD BOGASH
PRESIDENT

April 30, 1984

The Honorable Paula Hawkins
United States Senate
Washington, D. C. 20510

Dear Senator Hawkins:

I wish to respond on behalf of Wyeth Laboratories, a division of American Home Products Corporation, a manufacturer of vaccine products, to your invitation to comment on Senate Bill S.2117, the National Childhood Vaccine-Injury Compensation Act. We submit this written statement for the record of the hearing scheduled on May 3, 1984 before the Senate Labor and Human Resources Committee.

Let me first compliment you on your efforts on behalf of childhood immunization in the United States. This program, so fundamental to our nation's public health objectives, is certain to benefit from your personal interest.

The purpose of S.2117 to establish "a simple, no-fault, expedited, low transaction cost, nonadversarial, and effective national program for assuring the provision of just compensation to children and others who have sustained vaccine-related injury" is certainly a rational, societal judgment and one with which we would not quarrel. We must, however, respectfully disagree with limiting the program to a "non-mandatory alternative to the current tort system". We feel the program should be mandatory.

To provide compensation for the injured recipients of childhood vaccine is to remove but one of the threats to national immunization objectives. The manufacturers who assure continued development and availability of vaccines are also threatened. We, as well as vaccine recipients, can be victims of the excesses and vagaries of the current tort system. As an example, time periods for claims and suits by minors can exist until such minor reaches a majority age, placing a burden on all parties, a burden of unknown risk that may be as long as 20 years. Health care personnel are equally burdened. Removing, or denying recipients, the pertussis component of the vaccine may resolve the liability potential but obviously this is not a satisfactory public health solution. To preserve the immunization system and to extend it to other disease states, a singular legislative remedy is now required, one which covers all participants -- including manufacturers, distributors, and the people responsible for the administration of the vaccine.

The proponents of the current tort system speak of the need not to absolve manufacturers from liability for negligence. We support the continuation of manufacturer liability for any vaccine not meeting government standards.

We feel very strongly that the legislative remedy finally chosen must cover all participants of what is now a very effective immunization chain. Otherwise this chain could be broken at any point from the development of new vaccines through continuing availability of current vaccines, to the very point of advice, counsel and administration of the vaccine. For these reasons we submit that to be effective any Federal compensation program for vaccine injury must be an exclusive, mandatory remedy.

This is such a fundamental, overriding consideration, we chose to defer detailed comments on S.2117 to focus solely on this issue. We hope you will appreciate our concern.

Very truly yours,

Richard Bogash, Ph.D.
President

RB:emd

Statement by Lederle Laboratories,
Division of American Cyanamid Company for submission to the Senate Committee on Labor and Human Resources in response to the Committee's May 9, 1984 request for comments upon S.2117, the National Childhood Vaccine-Injury Compensation Act.

May 15, 1984

Vaccine Injury Compensation Legislation

Lederle Statement

Lederle appreciates the opportunity offered by the committee to comment upon S2117, The National Childhood Vaccine-Injury Compensation Act. Senator Hawkins' sensitive concern about the problem of no-fault vaccine injury has served to focus Congressional attention upon a complex and troublesome situation. It adversely affects both those unfortunately injured and the manufacturers who develop and produce the vaccines responsible for disease prevention.

The problem of devising a system for no-fault vaccine-injury compensation which is fair to the injured party, does not discourage private sector manufacturing and distribution or, research and development of new and approved vaccines and whose costs can be held within reasonable and predictable limits has thus far resisted solution.

While the problem exists in most developed nations, it appears that a greater measure of control is exercised in those countries than in the United States for three major reasons. One, existing systems of relatively comprehensive national health insurance; two, direct government ownership or indirect subsidization and/or protection from foreign competition of vaccine manufacturers; three, significantly lower rate of recourse to litigation in vaccine injury cases and more effective limitation of award amounts.

Historically, normal United States market forces have served this country well in maintaining a vigorous and effective domestic vaccine industry. The United States has long been the world leader in the development of new vaccines. There is every reason to believe such leadership can be maintained if actions are taken to balance certain negative conditions which have arisen within the past decade or so.

These negative conditions include increased costs, limitations on adequate pricing, extensive regulatory requirements, excessive litigation and awards, increased United States competition from relatively protected foreign manufactuers, a static or decreasing market for the basic vaccines and inadequate patent protection for research and development of new and improved vaccines.

If one of the objectives of S2117 is to assure a vigorous domestic vaccine resource, it is important to recognize that the problem is larger than vaccine injury compensation and perhaps more importantly, that actions taken relative to compensation will almost certainly affect other significant problem areas.

As has been pointed out in a study proposal by W. K. Mariner to the Department of Health and Human Services, "There is still surprisingly little analysis of the likely effects in the United States of possible alternatives [in vaccine-injury compensation], whether they would be consistent with legal tradition and the role of government in this country, whether they would be more or less costly than the present system, whether they would compensate all and only those entitled to compensation, and whether they would promote or hinder public health".

Lederle believes it is in the public interest that proposed reforms, whether legislative or regulatory, should be subject to such analysis before they are considered for passage or adoption. The Institute of Medicine of the National Academy of Sciences is presently engaged in a fact-finding study which should contribute valuable data for such analysis. (Lederle, among others, has made a major financial contribution to support the IOM study.)

While all vaccines may be considered preventive, the field is divided among several sub-categories such as: vaccines against communicable diseases (childhood and/or adult); vaccines against non-communicable diseases (such as tetanus); vaccines required by statute; vaccines which are optional.

Although the problems stated above affect all vaccines to one degree or another, S2117 is largely restricted to those which are mandated for children and deals specifically with only one of the inter-related problems -- that of compensation for vaccine-related injuries.

The following general comments concern selected provisions of S2117 and clearly indicate the need for further study to assure that the apparent solution of one vaccine problem does not exacerbate other related serious problems.

Non-Exclusive Remedy

The Bill provides a person who allegedly receives a vaccine-related injury with the option of bringing a lawsuit in the courts or to elect compensation. However, during the process of initiating the compensation option, it is possible under the Bill for a person to resort to tort law if that seems the surer way to a more favorable award. In addition, civil actions may be brought against the Secretary of H.H.S. where there is an alleged failure on his part.

Inasmuch as the existence of a compensation system will almost surely increase the number of claims and the unpredictability of tort law awards will not be relieved under these provisions, it is more than likely that the costs for no-fault cases will increase rather than be reduced. Since the probability of reforming state and federal liability law affecting these cases is rather remote, the non-exclusive remedy provisions of S2117 must be considered unacceptable to the public as well as manufacturers.

Surcharge

The "National Vaccine-Injury Compensation Trust Fund" which would be established under S2117 to pay claims under the Act would, in effect, merely create a middleman entity between the manufacturer and its insurance resource. All costs would still be paid by the manufacturer through the surcharge levy. The surcharge would cover only that part of the claims against the manufacturer brought through the compensation scheme. Claims awarded under the allowed tort option would be handled under a second system -- the present one.

As stated above, since it is highly probable that the existence of a government compensation source will increase the number of claims without conferring any higher level of costs predictability, it is by no means clear that the surcharge system offers any advantage for the manufacturer or the public. In addition, the added costs for administering the middleman "Trust Fund" could be substantial.

On a more fundamental level, the practice of holding manufacturers responsible for non-fault vaccine injuries is based upon the "deep pocket" assumption. The record of the substantial decrease in the number of United States vaccine manufacturers, which includes the loss of vaccine research resources, while not entirely attributable to claims, is compelling evidence that this approach is inappropriate for vaccines.

In producing vaccines which fully conform to standards promulgated and enforced by the federal government for use in immunization programs mandated by state governments, manufacturers are inappropriately penalized in having to bear the costs of no-fault injuries.

Lederle believes the public interest would be best served if funding for vaccine no-fault injury compensation were provided from general treasury funds.

Compensation Criteria

While the Bill provides for all feasible aspects of cause-and-effect assessment, in the many cases where casualty determinations cannot be absolute, the judgement of the assessor is subject to bias. A case in point would be the occurrence of Sudden Infant Death Syndrome (SIDS) in a three month old baby who displayed "prolonged inconsolable crying" (the language in the Bill) within 72 hours of DPT immunization at age two months. In spite of prevailing medical opinion that there is no casual relationship between immunization and SIDS, an assessment biased toward the petitioner could find such an event compensable.

The Bill directs the court to deny a petitioner only if it finds the injury is better explained by factors unrelated to the vaccine. However, such explanation and documentation would rarely be available in cases of SIDS, idiopathic epilepsy, mental retardation and other diseases which have a natural occurrence rate.

It seems clear that the injury assessment problems which have proven so troublesome and costly under tort law claims will be little or no less so under the proposed compensation system. Indeed, to the extent that the compensation court establishes a record of relative strictness in assessment, the available tort option will no doubt prove increasingly popular for claimants. The non-exclusive remedy provision of S2117 then creates a "Catch 22" situation which can defeat the basic purpose of the Bill.

Compensation Benefits

There can be no question of the morality and justice of compensating victims of vaccine injuries. A unique circumstance characterizes immunizations especially in the case of communicable disease. In addition to obtaining personal protection, the individual undergoing immunization is performing a public service.

However favorable the risk vs. benefit equation, the acceptance of that risk by the individual is not a personal decision, but forced upon him or her by law. This is, of course, entirely in the public interest, but since the responsibility for the individual's risk-taking is the government's, then the responsibility for the inherent and unavoidable no-fault injury which may result must also lie with the government.

We believe that the present tort actions against against the manufacturer in such cases and the manufacturer surcharge system under S2117 are entirely inappropriate. It is generally recognized that the existence of this anomaly has contributed significantly to the decline in the number of United States vaccine manufacturers.

Whether the costs are borne by the manufacturer, the medical professional involved or the government, it is in the public interest that adequate and timely coverage is available for no-fault injuries with a minimum of extraneous cost.

The compensation benefits offered by S2117 go beyond providing the expeditious coverage of medical expenses for families when they need it most. Many of the benefits offered are duplicative since they are already available under existing comprehensive state and federal programs. These include state and federally-assisted programs for disabled and crippled children, special education, vocational rehabilitation, mental health centers and others. An examination of such redundancy appears worthwhile since the administrative entity required by the Bill's provisions would constitute a new cost center.

A significant cost problem in tort cases is that of legal fees. It has been estimated by Senator Kasten, Chairman of Commerce's Consumer Subcommittee, that for every six cents awarded to an injured person in product liability cases, seven cents is paid for legal expense. The dual-remedy provision of S2117 serves to perpetuate such inequity. Similarly, it appears inappropriate for the Bill to provide mandatory coverage of attorney's fees for representation in no-fault compensation proceedings. Certainly, the additional attorney compensation of 25% of the entire award provided for in the Bill must be considered excessive.

Advisory Commission

The composition of the proposed Advisory Commission does not include members with the qualifications necessary to carry out or oversee the broad range of specialized responsibilities authorized by the Bill. These responsibilities include supplies of safe and effective vaccines, implementation of the program, vaccine surcharges and research.

However, sufficient experts and advisory committees already exist and the Secretary of HHS has the authority to assign employees, hire additional outside experts, establish informal committees and obtain public comment relevant to the needs of S2117.

The provisions which subordinate the authority of the Secretary to that of the commission in areas specifically included in the Secretary's responsibilities is still another instance of the unnecessary and costly redundancy imposed by the Bill. We believe these provisions should be amended to correct such deficiencies.

In the drafting of S2117, The National Childhood Vaccine-Injury Compensation Act, we believe Senator Hawkins has performed a significant service. The draft compels recognition of the inter-related problems which must be considered so that the public may be assured of a continuing and accessible supply of the present vaccines as well as of new and improved vaccines.

CONNAUGHT
LABORATORIES, INC.
Swiftwater, Pennsylvania 18370

Congress has recognized the long-standing efforts by the federal government to promote childhood vaccinations against communicable diseases and the influence of such efforts upon the adoption of applicable State legislation. Connaught Laboratories, Inc. agrees with and embraces the past and present efforts of the federal government and supports the concept of compensation for childhood vaccine-related injuries. Given the public health need for continued vaccine availability at a reasonable price, a national childhood vaccine injury compensation act providing compensation for present and prospective losses incurred or to be incurred as a result of suffering vaccine-related injuries is most desirable. Such a federal system of compensation should recognize the national scope of the public health issue and the interests served by continuing vaccinations while providing for a unified disposition of bona fide injuries resulting from receipt of certain childhood vaccines.

It is the position of Connaught Laboratories, Inc. that any childhood vaccine injury compensation legislation should provide for an exclusive remedy available to individuals injured as a result of receiving certain childhood vaccines. Legislation providing for compensation on an elective basis, that is, legislation permitting a choice between proceeding through the current tort system, or accepting compensation under the legislation, while providing recognition of the responsibility to establish a national vaccine injury compensation program, will not avoid the current adverse impact upon the continued availability of desirable childhood vaccines at a reasonable price. As currently written, S.2117 by its terms permits an election by a person assumed to have suffered a vaccine-related injury to pursue compensation under the program up to (but prior) to the entry of proposed findings of fact and conclusions of law, or a final judgment on a petition for compensation under the program, and to thereafter terminate the proceedings under the program in favor of prosecution of a civil action under our current tort system. Thus, irrespective of the seriousness of the injury, a claimant might weigh the value of the claim under the Federal Compensation Act against the potential value of a civil action arising out of the same incident. Requiring a manufacturer to contribute to a trust fund designed to provide compensation for certain childhood vaccine-related injuries while continuing to permit such manufacturer to be exposed to liability, in perhaps an amount greater than that which the federal legislation would provide, would have the result of continuous jeopardy to the supply of existing vaccines at a reasonable price, as well as providing for a chilling effect on the development of new vaccines.

In addition, any legislation providing for compensation of certain childhood vaccine-related injuries should be administered free from applicable regulation and influence by those unfamiliar with the nature of the significant public health interests served by vaccines and those who might be biased or prejudiced in view of some personal or financial circumstances.

Legislation providing for compensation of certain childhood vaccine-related injuries should be designed to provide compensation for losses presently and prospectively incurred while avoiding non-meritorious claims and continued potential catastrophic liability of health care providers and manufacturers. Neither health care providers nor the vaccine manufacturing industry would realistically expect absolute immunity from any and all action taken with respect to vaccines, however, to provide for federal legislation without due regard for the interests of all parties involved would not be in the best interest of society's public health goals.

Senator HAWKINS. We really do appreciate your coming and representing your company, Mr. Lyons.

STATEMENT OF JOHN E. LYONS, PRESIDENT, MERCK SHARP & DOHME, DIVISION OF MERCK & CO., INC., ACCOMPANIED BY WILLIAM B. FREILICH, COUNSEL

Mr. LYONS. Thank you, Senator Hawkins.

My name is John Lyons, and I am president of Merck Sharp & Dohme, which is the U.S. prescription drug division of Merck & Co. I am honored to offer testimony before this committee today.

Merck appreciates your strong interest in our Nation's childhood immunization program and welcomes the opportunity to present an industrial point of view concerning one very important aspect of it: The need for a fair and adequate compensation system for persons adversely affected by vaccinations in publicly funded programs.

We have high praise for the attention being given to this issue. However, we believe that S. 2117, as written, does not meet the needs for which it is intended. Specifically, we urge that the proposed legislation be modified to provide an exclusive remedy to the problem it addresses.

Merck's commitment to the development of vaccines and their use is a longstanding and well-recognized one. The returns to society on that commitment have been enormously gratifying, as vaccination has drastically lowered the toll of infectious diseases.

During the past four decades, Merck has been fortunate to have participated in the development of vaccines to prevent life-threatening and debilitating diseases such as measles, mumps, rubella, meningitis, pneumococcal pneumonia, and hepatitis B. Currently, with the largest private investment in vaccine research in the United States, scientists in our laboratories are now working on vaccines against a wide range of diseases, including hepatitis A, chickenpox, herpes simplex 1 and 2, neonatal meningitissepticemia, and Epstein-Barr virus.

While the progress toward disease prevention through vaccination has been meritorious, it has not been as productive as might have been hoped. There are several reasons for this, including the problems associated with liability in public health immunization programs.

It is obvious that the vaccine industry in the United States is not as strong a resource today as it once was. Yet, the future of domestic vaccine supply depends on the continued willingness and ability of the pharmaceutical industry to produce adequate quantities of vaccine and to develop the vaccines of tomorrow. Clearly, a major impediment to commercial initiatives in this field is the unresolved public policy problem of liability in mass vaccination programs.

As we have seen today, although most vaccines are extraordinarily safe, they can be associated with adverse reactions in a small percentage of the people who use them. Most of these reactions are minor and self-limiting, but some very rare reactions can be harmful, even fatal.

Seldom, if ever, is anyone at fault when these unfortunate incidents occur. Yet, still, when millions of persons are vaccinated, some will experience adverse reactions.

The courts have understandably sought to compensate injured persons. It is true that the past experience of manufacturers with regard to court decisions cannot justify changing the present tort system of compensation. However, the unpredictability of the future is clearly a disincentive for vaccine innovation in the United States. It is a major reason several manufacturers have abandoned the vaccine business in recent years.

A workable vaccine compensation system should serve three objectives beyond its primary purpose of helping the victims of adverse reactions: first, it should increase the willingness of the public to participate in immunization programs; second, it should help assure the continued willingness of physicians and other health care professionals to conduct immunization programs; and third, it should encourage manufacturers to provide vaccine not only for existing programs, but also to devote substantial resources to the discovery and development of new vaccines.

To reach the first objective, a compensation system must provide a fair, easily accessible, and prompt remedy. The present tort system amounts to a lottery. It has not worked well and has resulted in many problems. If a compensation system promply and fairly compensates all injured persons for their actual losses, there is no need to continue the tort system alternative. A fair compensation system will accomplish this objective and help provide for the other two. But truly assuring the availability of vaccines and immunization programs under our current system can only be accomplished by creating an exclusive remedy for injured vaccines.

The existing tort system poses a number of problems, the most significant of which is its unpredictability. Courts in each of the 50 States are free to develop new rules of liability at any time and without prior notice. Even when the basic rules are not changed, the strong and understandable desire of juries and courts to compensate injured persons can lead to determinations of liability that are against the weight of medical evidence. Both health care professionals and manufacturers have, on occasion, found themselves liable for circumstances over which they could exercise little or no control.

For example, manufacturers have been held responsible for not warning vaccinees or their parents or guardians of all risks involved in receiving a vaccine, even though the vaccination program was controlled and run by public health officials. Confronted with this unpredictability, manufacturers and health professionals cannot accurately estimate their risks nor plan their insurance requirements.

The tort system also offers little protection against groundless or trivial claims filed for their nuisance or settlement value. Such cases often generate substantial legal costs that can multiply to significant proportions if the program is highly publicized such as occurred with swine flu in 1976.

In conclusion, we would like to leave you with two principal thoughts. First, a dual compensation system that offers a choice of either going to the tort or to the no-fault concept does not alleviate the problems I have cited. There is, however, a place for the tort system in a compensation program.

For example, when a manufacturer fails to produce a vaccine in accordance with Government standards or a health care provider fails to administer the vaccine in accordance with medical standards, the tort system should be open for an injured party to recover. But, to accomplish the objectives of fair compensation, the tort system should be eliminated from any other type of action. Therefore, our second conclusion is that only a compensation system embracing the concepts of no-fault and exclusive remedy can provide the basis for truly fair and workable legislation.

There is no easy solution to the vaccine liability problem, but we believe some action must be taken by the Government to avert impediments to future immunization efforts. With the changes we have suggested, S. 2117 could be a very productive step in the direction of disease prevention.

Thank you, Senator.

Senator **Hawkins**. Thank you very much, Mr. Lyons.

Mr. Eaton, may we hear from you?

STATEMENT OF KENNETH L. EATON, INTERGOVERNMENTAL OFFICER, MICHIGAN DEPARTMENT OF PUBLIC HEALTH, ACCOMPANIED BY VINCENT J. LEONE, ASSISTANT ATTORNEY GENERAL, STATE OF MICHIGAN

Mr. **Eaton**. Thank you, Senator Hawkins.

May we add to the very justifiable commendations you have been receiving for your excellent leadership in this issue. It is one that has been neglected for far too long, and we wish to offer our continued interest and cooperation.

The Michigan Department of Public Health is involved in this from several different points of view, some of them potentially conflicting. On the one hand, we are involved as a manufacturer of vaccines. We are also involved in protecting the public health. As you have heard today, there are different sets of problems on both sides of that issue.

We are also involved in intensive research and development about vaccine improvements and have been involved in biologics and the development of vaccines for several years.

Rather than to add to the already excellent testimony you have received from scientific experts and others about the medical and scientific issues, we have chosen to emphasize our point of view as public policy entities and to discuss with you some of the problems we have faced and how we feel your legislation can benefit us.

We are, as you mentioned, one of only two Government agencies directly involved in the production of vaccines. This makes us perhaps more acutely aware than many health departments might be of the need for a publicly coordinated compensation system which will encourage the production of vaccines by providing for the care of those few who are unavoidably injured by adverse reactions.

It is our concern for vaccine-injured children as well as for children who may suffer a communicable disease due to the potential unavailability of vaccine which leads us to support your proposed legislation in Senate bill 2117.

We are currently involved, unavoidably, in a number of lawsuits because of our production of vaccines. Frankly, a tempting solution to this potential liability on the part of the Government which deals not only with the economic pressures it brings, but with the political implications it brings, is to consider joining the ranks of other former vaccine producers and cease production of vaccines to protect ourselves. We resist and dislike this solution because of our dedication to protecting children against communicable disease, but we must acknowledge that the increasing pressure of escalating costs and a heavy volume of litigation may force us in the foreseeable future to discontinue this operation or seriously consider such action.

However, in the meantime, and still as public health advocates, we continue to produce over a million doses of DPT vaccine a year, despite the increasing complications related to several lawsuits.

As the committee has heard and reported on several different occasions, we all acknowledge the very important role that vaccines play in controlling and eradicating many diseases, and yet, on the other hand, we also understand that there seems to be a predictable small number of adverse reactions which can be very serious.

We are involved in research and development activities and do anticipate in the future some improvements in these vaccines, but it is important to know that unavoidable injury to children will remain with us for some time. Advances do not seem on the offing in the extremely near future. I won't go into details. If we can be helpful to the committee in providing any information about the research that we are conducting or other activities, please be assured that we will be happy to provide that, but have not chosen to take your time today; I know you are running short.

We do have some reservations and some concerns about the legislation which Mr. Leone and I would like to mention to you. However, I would like to make the point that as a new framework for a system of restitution to vaccine-injured children, this bill is far, far superior to the only other avenue currently available, and that is lawsuits and this court system which you have heard so much about.

I would like to ask Mr. Leone to make some brief remarks about what we face in that respect, and then I have a few concluding suggestions.

Senator **Hawkins**. Thank you, Mr. Eaton.

Mr. Leone?

Mr. **Leone**. Senator, my name is Vincent Leone. I am assistant attorney general for the State of Michigan.

I think Mr. Eaton has indicated that the Michigan Department of Public Health is a unique position on this issue, both as public health administrators and as producer of vaccines for over 50 years.

I am here today not only as a public health advocate and as a lawyer defending the Michigan Department of Public Health in a number of lawsuits, but as the father of two boys. I think the most saddening aspect of my work is listening to a mother's anguish when her child's condition, her second-grader's condition, prevents him from even finding the bathroom in the school and even knowing where he is once he searches for it.

In all candor, in the cases that I have been involved in and in case studies that I have read about, I firmly believe that very, very few children have been injured by vaccine.

I even think under this no-fault system, which would eliminate the issue of negligence and perhaps lessen the burden of causation, that very few children would qualify under the system.

I still support the bill, and the department of public health supports the bill, because I think it would promote the reliable vaccine supply, which is the greatest concern to health officials. It would also provide a quicker and more straightforward way for parents with injured children to learn whether their children are hurt by an act of man or an act of God.

I think the written comments that have been submitted to your committee outline the problems that the department has with the tort liability system and what the department's role and rights should be under a no-fault system, so I won't reiterate those at this time.

However, I think it should be said that the specter of lawsuits, and even the existence of a no-fault system, may suggest to millions of parents out there that there are problems with the vaccine. I think perhaps we have greater problems with the tort liability system. We have such problems with that that we developed a workmen's compensation system decades ago. Many States have no-fault car insurance statutes.

Frankly, I believe that the health of our children, the health of the public in general, is too important to be left solely to attorneys.

With the few reservations that we have indicated in our written comments and any that you care to address to me today, the Michigan Department of Public Health supports the bill.

Thank you.

Mr. EATON. We would like to make one or two suggestions, Senator. Mr. Leone indicated a few of his reservations.

We do have some concerns about some of the recordkeeping requirements, not in opposition to the need for information, but, for example, in mass immunization settings meeting the requirement or assuring that requirements are met to place information in each individual's permanent medical record will be very difficult. In some occasions in mass immunization settings it may even be impossible to insure. Sometimes there are no permanent records available to us.

We would like, also, to raise a question about the wisdom of imposing a surcharge of any amount on vaccines to finance the compensation program. Since many of the vaccines encompassed by this bill are going to be obtained by the States with public funds, much of that Federal grant funds, a surcharge on the vaccines will simply raise the price which the Federal Government must pay through grants to the States in order to meet the public need. For those who privately pay for their vaccines, there really is little opportunity to shop for less expensive vaccine, and perhaps there is no equity in being required to pay a higher price for a vaccine which has caused a no-fault injury in the past.

With the precipitous decline in private manufacturers of vaccines, one might even wonder whether some of the manufacturers would even object to its product being priced out of the market. We have seen many leave the market for a similar reason.

As for a department such as ours, we have a question as to how a surcharge would be imposed on its vaccine which is produced at the expense already of the Michigan treasury and distributed to its citizens free of charge. It is difficult for us to conceptualize an equity in paying a surcharge again to the national compensation fund with that respect.

We will be happy to work with you in terms of alternatives. You have received several suggestions in other testimony.

With these few reservations, we support S. 2117. It clearly is an innovative effort to provide just compensation for vaccine-injured individuals. We hope it will be at least one good step in encouraging the production of vaccines to control communicable disease and thereby promote public health, which is a big, big priority to us.

We offer our continued cooperation and assistance, and again wish to thank you for your leadership.

[The joint prepared statement of Mr. Eaton and Mr. Leone follows:]

STATEMENT OF

KENNETH L. EATON
INTER-GOVERNMENTAL OFFICER
MICHIGAN DEPARTMENT OF PUBLIC HEALTH

and

VINCENT J. LEONE
ASSISTANT ATTORNEY GENERAL
STATE OF MICHIGAN

before the

COMMITTEE ON LABOR AND HUMAN RESOURCES
UNITED STATES SENATE

on

S.2117
THE NATIONAL CHILDHOOD VACCINE INJURY
COMPENSATION ACT

MAY 3, 1984

The Michigan Department of Public Health (MDPH) is the agency in the State of Michigan responsible for the protection and promotion of the public health of the citizens of Michigan. MDPH has been a recognized leader in the identification and eradication of communicable diseases due principally to its ongoing commitment to a state laboratory for the development of vaccines and other biologics for distribution within Michigan. With over 100 years of public health experience, and as one of only two government agencies directly involved in the production of vaccines, MDPH is uniquely aware of the need for a publicly coordinated compensation system which will encourage the production of vaccines by providing for the care of those few who are unavoidably injured by these vaccines. It is this concern for vaccine-injured children, as well as any children who may suffer a communicable disease due to the unavailability of a vaccine, which leads MDPH to support Senate Bill 2117, entitled "The National Childhood Vaccine Injury Compensation Act".

MDPH is currently involved in a number of lawsuits because of its production of vaccines. An easy, but shortsighted solution to this potential liability is to join the ranks of other former vaccine producers and cease production. However, MDPH fears that such an action will jeopardize its ability to ensure that hundreds of thousands of children are provided with protection against communicable diseases each year. Thus, as public health advocates, MDPH continues to produce over a million doses of DTP vaccine a year, despite this ever increasing exposure to lawsuits.

Unfortunately, as all recognize, the protection provided by these vaccines has its drawbacks. Some children are injured by the vaccine itself. Despite anticipated improvements in these vaccines, the potential for unavoidable injury to children will remain for some time. Senate Bill 2117 will provide an equitable system for identifying and providing for the care of children injured by vaccines. This is not to say that MDPH supports this bill without reservations. However, as a new framework for a system of restitution to vaccine-injured children, this bill is far superior to the only other avenue currently available -- a lawsuit.

The current method for seeking redress of injuries by the institution of a tort action in the courts is unworkable for both the producer and ultimate user of these vaccines. First, since virtually all recipients of the vaccine are children, the time period for bringing an action in the courts is often as long as two decades. This prevents the vaccine producer from having any realistic estimate of its potential liability or enable it to modify its activity in a timely fashion to improve its operations. For the child, this may mean that his/her lawsuit is not pursued expeditiously; and as the facts surrounding the inoculation become more remote with time, the costs of litigation increase.

Secondly, the traditional principals for maintaining a tort action may be subordinated to the greater social issue of the protection of the public against the spread of communicable diseases. Under this country's jurisprudence, a maker of a product generally has a duty to provide a safe reliable product to the ultimate user. If the producer does not believe it can clearly meet this duty, it will often cease production. However, these vaccines must be produced in order to control communicable diseases notwithstanding the recognized risk involved in their use. Thus, in the face of this higher social goal, the courts may be more willing to require that compensation be paid by a vaccine producer, who is not negligent, for a vaccine which nonetheless unavoidably injured a child.

A private manufacturer theoretically absolves itself from responsibility for a vaccine-injured child if it did not negligently manufacture the vaccine, and it provided the accepted warnings against contraindications or the potential for adverse reactions. To the injured child needing compensation in order to effectively operate in society, this is of little consolation. Yet, the further the court system strays from traditional notions of liability of a producer to its customers for the sake of a higher social goal, the greater the risk that the few remaining private manufacturers of vaccines will abandon this already unattractive endeavor.

Finally, it should not be forgotten that the traditional tort system is an adversarial process. Opposing sides argued the merits of their case with the hoped for result that the truth will prevail. In vaccine suits, external factors may tilt this balance to the advantage of one party. For example, since children are often less than a year old when they receive their inoculation, almost any malady that the child experiences throughout his/her life can be arguably attributed to the vaccine. Yet, many genetic or idiopathic conditions do not become apparent until a child is older.

On the other hand, few of the reactions to these vaccines are easily identifiable or can be shown to be exclusively caused by the vaccines. Thus, children who cannot produce a documented history of inoculations, immediate identifiable reactions, and major injuries may be unable to seek recourse through the tort system.

MDPH's involvement in vaccine lawsuits places it in the uncomfortable position of pursuing both its constitutional mandate to promote the public health by identifying those suffering from health-related problems while concurrently protecting the public treasury from meritless claims. Yet, the position of private manufacturers is no less comforting as they are expected to meet the nation's demand for improved vaccines with fewer and fewer adverse reactions under an adversary legal system which by right challenges every initiative taken by them. Can a meaningful dialogue take place between all concerned parties on the relative benefits and risks of altering vaccine immunization policy when this public health issue has serious ramifications on the financial liability of the participants?

The adverse impact of the tort system on these public health issues has convinced MDPH that the better route for all parties is the no-fault compensation system proposed by HB 2117. Public health concerns would be best served if the new system was the exclusive remedy. However, MDPH believes that those truly injured by vaccines are not seeking a windfall from their tragedy and will opt for the certainty and timeliness of relief under this equitable compensation system over the vagaries of the tort liability route.

MDPH does have reservations about certain aspects of the bill as now written, which it believes should be revised or clarified. One concern is over the costs and responsibility of the extensive recording requirements provided for by the bill. Though such requirements are helpful in processing the claims of those few who are injured, the responsibility for ensuring that the required information is placed in each individual's permanent medical record will be burdensome, if not impossible, especially in the mass immunization setting.

A second concern is for the rights of the producers of vaccines in the compensation process. Though MDPH does not propose an adversary system, it suggests that a vaccine producer should have the right to submit information which, in the words of the bill, better explains the cause of the illness or event unrelated to the administration of the vaccine. A vaccine producer is an interested party in this process since the federal government obtains a subrogated right to sue it for negligence and raise its vaccine surcharge upon an award of compensation under a no-fault system. Furthermore, if vaccine production is to be encouraged as envisioned by this bill, the subrogation of a public plaintiff, the federal government, for a private one, the injured party, should not occur except where it appears that there has been a clear case of negligence on the part of the producer.

MDPH questions the propriety of imposing a surcharge of any amount on vaccines. Since many of the vaccines encompassed by this bill will be obtained by states through federal grants, a surcharge on the vaccines will simply raise the price which the federal government must pay in order to meet public need. For those who pay privately for their vaccine, there is little opportunity to shop for a less expensive vaccine or any equity in being required to pay a higher price for a vaccine which has caused "no-fault" injuries in the past. With the precipitous decline in private manufacturers of vaccines, it is debatable whether a manufacturer would even object to its product being priced out of the market. As for MDPH itself, the question remains as to how a surcharge would be imposed on its vaccine which is produced at the expense of the Michigan Treasury and distributed to its citizens free of charge.

Finally, MDPH cannot entirely accept the vaccine injury table as written, and would like the opportunity to provide imput on the determination of recognized reactions and the time period within which the reactions are to occur for compensation to be provided to a petitioner.

In conclusion, with these few reservations, MDPH supports House Bill 2117, the National Childhood Vaccine Injury Compensation Act, as an innovative effort to provide just compensation to vaccine-injured individuals, to encourage the production of vaccines to control communicable diseases, and to thereby promote public health.

Senator Hawkins. Thank you for your being so helpful.

I like to tell everyone that I brought my attorney and my doctor with me, too. Robin Rushton and Dr. David Sundwall are watching over me with great care.

Your department, Mr. Eaton, of health and biologics is only one of two State governmental agencies, as I understand it, that is involved in the production of vaccines. What prompted your agency to get in this area?

Mr. Eaton. It is historic, Madam Chairman. It was basically the essence of our health department's efforts when it began. As Mr. Leone said, I think it has been about 40 years since we have been in this.

Our initiative was spurred by a need to be directly responsive to the immunization needs of our own population. We had a setting within our legislature that was conducive to our responding immediately to it, and from that point it has been somewhat of a tradition of our department.

Mr. Leone has also been digging deeply into the history because of his involvement with our lawsuits and may wish to add something to that.

Mr. Leone. I can just say, Senator, that Dr. Prokindrick and Dr. Elderling from the Michigan Department of Public Health developed the first effective pertussis vaccine back in the 1930's and tested it in Grand Rapids, where it had the highest incidence of pertussis in the world at the time.

That is a problem that I think some of the other participants in this meeting have touched upon. When you have something that is so highly successful, the ability to improve it, especially under a tort liability system that challenges every change you make, becomes very difficult.

Senator Hawkins. Are you aware of the Japanese vaccine for pertussis?

Mr. Eaton. I am not personally familiar with it, Ma'am, no.

Senator Hawkins. I believe you recently received an NIH grant to enter research for a safer vaccine. Is that correct?

Mr. Eaton. Yes, Ma'am, we did.

Senator Hawkins. Was the grant adequate to cover your costs?

Mr. Eaton. Probably not. Most of them don't.

We are just beginning that work. The grant was awarded within the past few months. We do hope that it can make a contribution to improved vaccines and are optimistic that it can, but I would again point out that that is slow work. It is difficult and tedious work to do.

We would be more than pleased to keep the committee informed about our progress and provide you with information as to what specifically we are attempting to accomplish.

Senator Hawkins. Thank you.

Does the department of health and biologics charge for DPT dosage?

Mr. Leone. Nothing.

Mr. Eaton. We don't. We don't charge unless, for some reason, an out-of-State agency finds itself short of the vaccine and asks us to provide it. We don't make an effort to do that, but we do try to keep a sufficient stock so that we can occasionally respond to that.

Then we do ask them to pay what we call costs. I am not really sure what it is. We are not even sure what it costs us to produce a dose of that vaccine, but we distribute it within the State free of charge.

Senator HAWKINS. Outside of the State do you make a profit?

Mr. EATON. No, we wouldn't make a profit. We would try to estimate what it costs us to produce it and ask them to meet that cost as reimbursement.

Senator HAWKINS. I know that Michigan, like every other State, must be trying to reduce its cost of government. Is your vaccine program in any danger?

Mr. EATON. I would say so. We have not entered into highly formal discussions with the legislature about the prospect of discontinuing or cutting back on the operation, but it is becoming increasingly difficult for us to face the prospect of the added cost for continued improvements and updating of our laboratory, and there are, as you might understand, several who would question the need for the use of public funds in the State of Michigan to produce vaccines which many people think are commonly produced and will dependably be produced in the future by private manufacturers. So it is an annual discussion that we have incessantly, and each year we feel a greater vulnerability to our capacity to defend the propriety of continued public expenditures for this purpose. It is going to become a more difficult problem, we predict.

Senator HAWKINS. Thank you.

Mr. Lyons, what is the status of future vaccines being developed by Merck?

Mr. LYONS. As I pointed out in my testimony, we are currently working now on hepatitis A vaccine, herpes simplex 1 and 2——

Senator HAWKINS. Chickenpox?

Mr. LYONS. Chickenpox, the varicella vaccine. There is a vaccine that we have been working on since about 1962, and we have just completed its first use in a large clinical trial. It probably won't be available for another 2 or 3 years. That additional development time could be rather long.

Senator HAWKINS. Do you have a history of upgrading your measles vaccine?

Mr. LYONS. Yes, we do. Our vaccine research and development is directed not only toward vaccines to protect against diseases for which no other vaccine is available, but also current vaccines. The first measles vaccine that we produced was in 1963. That was a product that required the coadministration of gamma globulin because of a high incidence of reactogenicity. We improved that and came out with another vaccine in 1969. Since that time, we have improved it further. We also just came out with a new pneumococcal vaccine. The original vaccine was a 14-valent vaccine, and we just came out with a 23-valent vaccine. Vaccine R&D is an ongoing process.

Senator HAWKINS. We really want to praise you as a committee for coming today and helping us with this record. We may not agree on every point and paragraph of S. 2117, but I believe we all agree on the need to modify the current method of compensating children for injuries. I think these children have an urgent need and deserve simple justice quickly. That is not always the role of Government, to move very rapidly.

We really appreciate your willingness to be with us today, all of the witnesses who participated in the development of the record. I would like to praise the two vaccine manufacturers who came here today. I urge you to continue to upgrade your vaccines and continue research on safer vaccines. I think that is probably the bottom line that we have here as a mission for the future and as we look at the past. We have to resolve how we address the solution to those problems of the past.

[Additional material supplied for the record follows:]

U.S. Department of Justice

Office of Legislative and Intergovernmental Affairs

Office of the Assistant Attorney General
Washington, D.C. 20530

12 JUN 1984

Honorable Orrin G. Hatch
Chairman
Labor and Human Resources Committee
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

This letter is in response to your request for the views of the Department of Justice on S. 2117, the "National Childhood Vaccine-Injury Compensation Act." For the reasons set forth below, the Department of Justice recommends against enactment of this legislation.

S. 2117 would create a federal program to compensate persons suffering certain injuries occurring after the administration of specified childhood vaccines. We oppose the bill because, at bottom, no special justification has been proffered necessitating an entirely new set of judicial procedures supplementing existing remedies provided by law. In addition, specific provisions of the bill, summarized below, are objectionable.

The bill would supplement, but not replace, the existing tort system of determining liability. Under Section 2111(b), an individual would have a choice of suing in tort or seeking compensation under the statutory program but could not seek recovery in tort after a decision under the program. The extraordinary provision of a choice of remedies with respect to injuries allegedly incident to childhood vaccines but not other injuries compensable through tort litigation can only lead to confusion and duplicative litigation. Since existing tort remedies remain available, until a decision is made or judgment is entered under the program, see Section 2111(c), the bill could permit results inconsistent with those achieved after a full trial on the issues. We do not perceive any reason for giving litigants "two bites at the apple."

Also, while the very detailed provisions of the bill may be viewed as an attempt to narrow the issues in dispute, our experience in the courts, including experience gained under the Swine Flu Program of 1976 (P.L. 94-380), indicates that the nature of illnesses and the date of first onset of symptoms of the illnesses would be hotly contested in many instances. The bill would determine compensation based on the nature of the illnesses and date of onset of symptoms. Thus, the detailed provisions of the bill are not likely to achieve their apparent purpose of limiting disputes before the courts.

If the bill were acceptable in principle, many of the specific provisions would require amendment. For instance:

1. Section 2113(d)(1) contemplates proceedings before magistrates or special masters. There is no reason why judges should not exercise their judicial function in these proceedings as in any other judicial proceedings seeking recoveries for personal injuries.

The bill does provide that special masters or magistrates shall not "exercise the ultimate judicial responsibility, which shall be retained by the court," Section 2113(d)(1), and that a petitioner can seek a *de novo* determination by the court if he is dissatisfied with the magistrate or special master's findings or conclusions and that the court may review the rulings on its own motion. The duplicative proceedings permitted by the bill are quite unlike magistrates' proceedings authorized under 28 U.S.C. § 636(c), because the petitioner is compelled to consent to trial before a magistrate in the first instance and because the magistrate's determination is not binding on the petitioner or the court. Further, the respondent should have the same right to appeal an arguably erroneous magistrate's determination to a district court as does the petitioner.

2. The bill contemplates *ex parte* proceedings. Section 2113(b)(1). In the context of this legislation, the nature of those proceedings is vague. As drafted, the bill may turn out to be unworkable administratively; in any event, a full hearing would be important to permit fair determinations of the factual issues in these proceedings.

3. Section 2113(f)(1) states that a decision to provide compensation shall constitute an obligation of the United States and shall be backed by the full faith and credit of the United States. This obviously is intended to permit the general treasury to be reached rather than merely limit recoveries to the trust fund created by the bill. If this were otherwise deemed desirable, it is not clear what effect the chosen language would have on payments.

4. Section 2113(e)(2) provides that an appellate court shall review the district court's decision to determine whether the findings are "unsupported by substantial evidence." This is usually the standard applied to review of an administrative agency's findings rather than to a court's findings. We doubt whether this standard should be utilized in this legislation if district courts are to make the initial decisions.

5. Section 2117 provides for affirmative suits. We assume that suits on behalf of the Secretary would be filed only if authorized by the Attorney General or his designee and that the Justice Department would represent the Secretary in all litigation. It might be desirable to make this requirement explicit.

6. Section 2117(a)(2) authorizes the district courts to refer the records of certain proceedings to the Secretary and to the Justice Department with recommendations with respect to investigations and/or commencement of civil actions. This provision is apparently unique. We are unaware of any other circumstances where a court is permitted to interfere with the Executive's prosecutorial and investigative prerogatives in such a manner, and see no reason why a court should be given this authority here.

The Department of Justice recommends against enactment of this legislation for the reasons set forth above.

The Office of Management and Budget has advised this Department that there is no objection to the submission of this report from the standpoint of the Administration's program.

Sincerely,

(Signed) Robert A. McConnel

Robert A. McConnell
Assistant Attorney General
Office of Legislative and
Intergovernmental Affairs

STATEMENT

BY

Mrs. Marge Grant
Mother of Scott Grant, a DPT Vaccine Victim
and
Chairman, Research Committee of Citizens For Free Choice
In Immunizations, State Of Wisconsin

TO

COMMITTEE ON LABOR AND HUMAN RESOURCES
UNITED STATES SENATE
WASHINGTON, D.C.

Hearing held: May 3, 1984

SENATOR HAWKINS, SENATOR HATCH, COMMITTEE MEMBERS:

I am pleased to honor your request to contribute to the diverse collection of views on S. 2117, The National Childhood Vaccine Injury Act, with this written testimony for the hearing record.

As the mother of Scott Grant who will have his 23rd. birthday one month from tomorrow, the statements that follow are a reflection of my husband Jim and my views as we perceive S. 2117, based upon our past 23 years of personal experience. Not only from providing Scott with round the clock care ever since he became incapacitated from the severe brain damage inflicted upon him by Parke Davis' DPT vaccine at 6 months of age ... but from at least 10 years of litigation, which involved more encounters with unscrupulous maneuvering by top vaccine officials within the govenmental vaccine regulatory agency and this pharmaceutical company than anything else.

As desperately as we need compensation for Scott's permanently disabled condition, we cannot permit this to eliminate our moral obligations and commitment to continue to expose the whole truth about DPT and exercise everything within our power to prevent any more children from being maimed and killed from its use. And it is for this precise reason ... as well intended as S. 2117 may be ... we find it impossible to support it in its present state. This is of great disappointment and we deeply regret after waiting 2 long years for the creation of this crucially needed legislation, that it is necessary for us to take this stand. What is most heartbreaking is the hundreds, perhaps thousands of additional vaccine damaged children that may have resulted by the continued use of this admittedly dirty-imperfect vaccine over the additional 2 year period.

Not to mention how may more years it will be forced upon our innocent children while the political game-playing continues.

Because of S. 2117's extreme length and ambiguous language, time nor space will permit comment on its entirety ... and the following reflects just a few of the flaws in this bill as we perceive it.

··· We cannot accept the repeated term that this bill has provisions that will create mandates for development of a safer vaccine. With the manufacturers' past well established deceptive reputation, this permits them to continue to hurt children right and left. One might say, instead of the present vaccine hurting 5,000 children each year ... it will be acceptable if 4,999 get hurt with a different ... but not truly SAFE vaccine. It is our firm position that unless manufacturers are absolutely forced to full accountability, they will never substantially improve this vaccine. Full accountability, includes an obligation to carry adequate mal-practice insurance with the premiums paid fully out of their own pockets, not the taxpayers'. Then, and only then, will they rapidly find a way to produce a SAFE vaccine.

··· With the assumption this bill adequately provides a mandate for all health care providers to report all adverse reactions: Again, with their past reputation in this regard we are NOT convinced they will carry through with this responsibility, unless, a heavy and firm legal penalty for their noncompliance is enforced.

··· At the very least, the title of a "NO-FAULT" compensation system is an insult and painfully offending to the vaccine victims and their families, who certainly do not need salt poured into their open wounds, by a title that absolves the very ones who hurt them.

··· The special master or magistrate shall be an attorney ... he will have the power to accept or reject any petition ... there is nothing that qualifies him to make such determination by himself and he could conceivably deny most claims ... the impact of which would permit the same 50 year old lies ... that severe reactions are indeed very rare.

Wilma Gundy
5923 Urban Court
Arvada, Colorado 80004
303-422-0598

April 18, 1984

Senator Paula Hawkins and Committee Members:

As a victim of the swine flu vaccine, I welcome this opportunity to share written testimony with you on S. 2117, the National Childhood Vaccine-Injury Compensation Act of 1984.

I am one of 46,000,000 Americans who heeded the government's promotional program to stop the chain of contagion of a "killer" disease in 1976 and was vaccinated for swine flu on November 26, 1976. Three weeks later, my feet, legs, arms, hands and the left side of my face and tongue began to turn numb. I felt as if I had been injected with novocaine. Besides the numbness, I felt extremely exhausted and weak.

I spent the next three and one-half years going from doctor to doctor and submitting to test after test before my illness was diagnosed in 1980 by Dr. Charles Poser as "sensory" Guillain-Barre' syndrome (GBS). There are, I've since learned, two types of GBS: the acute form in which the victim becomes paralyzed and the sensory form in which the victim suffers sensory loss, weakness, fatigability and shakiness. A large percentage of victims with paralytic GBS recover; many victims of sensory GBS do not. The damage to the peripheral nervous system does not heal. It is the opinion of Dr. Poser that the damage I have suffered is permanent and that I will not recover.

Although I am able to do only one-half of what I did prior to taking the vaccination, I feel I am among the "fortunate" victims of swine flu vaccine. Many others are paralyzed, have lost the use of their hands, or suffer some other severe disability. My life philosophy embraces a commitment to helping others. Not just for my own sake, but in the hope I might be able to help these other victims who are severely handicapped, I have devoted many hours over a period of several years to researching exhibits developed by the National Steering Committee for Swine Flu Plaintiffs, medical articles, and the claims and lawsuits of other swine flu victims. It is with this background of personal experience, research, and commitment that I volunteered to testify before your committee.

Foremost, I want to commend you, Senator Hawkins and members of the Labor and Human Resources Committee, for sponsoring this legislation, and for the hours and hours of study, writing, and discussion which have resulted in S. 2117. A national compensation bill for vaccine victims is acutely needed. There are several commendable features of S. 2117, but space does not permit me to talk about them. Rather, I shall direct my comments on several points which I believe should be elaborated or changed.

First, I shall elaborate on why I agree that pursing compensation for vaccine injury through the courts is unsatisfactory. In 1978, under provisions of the Swine Flu Act, I filed a routine claim requesting compensation for my medical expenses and for the hundreds of days of work I'd lost. After my claim was technically denied because the Justice Department ignored it, I filed a lawsuit.

At my trial in June, 1980, two neurologists testified I have Guillain-Barre syndrome; five doctors testified my illness is due to the swine flu vaccination, and four different objective tests supported that opinion. The Justice Department called one witness: Dr. James Austin of the Department of Neurology at the University of Colorado Medical Center who testified he "did not know what Mrs. Gundy's disease is, but whatever it is, it is not due to the swine flu shot." My suit, heard in the 10th Judicial District before Judge Sherman Finesilver, was denied. I appealed the decisions, and after three years of waiting, the appeal was also denied.

Judge Finesilver's opinion in my suit set a nationwide precedent to deny liability unless the victim developed paralytic GBS within ten weeks of taking the inoculation. I have heard from other victims who, like me, had a "preponderance of the evidence" on their side in their trial, but whose suit was denied.

In the introduction to S. 2117, Senator Hawkins comments that "Our legal claims system is a slow, expensive, and uncertain process." Slow? Indeed. It has now been 7-1/2 years since I first became ill. Not only have I received no compensation to date, but through the judicial Torts process, I never shall. Expensive? Yes. To date, expenses incurred in my lawsuit against the Government is slightly over $17,000. Uncertain? No. I say not uncertain, because the pursuit of justice for swine flu vaccine victims has proved quite certain: any claim or lawsuit that does not fall within the Government's established guidelines of paralytic GBS developed within ten weeks, or prior to January 31, 1977, will not be compensated.

According to the latest statistics I've been able to get from the Torts office of the Justice Department, 4,075 Americans have filed claims against the Government. Two-thirds of the claims filed, 2,710, have been denied. Under the provisions of the Swine Flu Act, 1,536 of those whose claims were denied have chosen to file lawsuits. Of the suits filed, many have been dropped or settled out of court for a small percentage of damages asked. Nationwide, of suits which have gone to trial to date, plaintiffs have won 21, the Government 110 - a ratio of 1 in 5.5. The Government has appealed almost all of the suits it lost and has won on appeal.

The 10-week cutoff date after which liability is denied was established by a study conducted by Dr. Lawrence Schonberger for CDC. This cutoff period has been the issue of numerous lawsuits. The "smoldering" theory of the etiology of GBS is held by many neurologists. They theorize that either the victim develops a "smoldering" case of GBS from the vaccine which is then precipitated by a virus or infection, or the vaccination affects the immune system, making the victim susceptible to catching the disease. Thus, a vaccinee may develop GBS weeks or months after the vaccination. For medical documentation on tnis point, I refer you to "Late Onset of Guillain-Barre' Syndrome" by Charles M. Poser and Peter O. Behan in *Journal of Neuroimmunology*, 3, (1982) 27-41. Hence, the timeline given for occurrences of a reaction to a vaccine is NOT long enough.

I call this to your attention because GBS may result from other types of vaccines, not just influenza. Moreover, some doctors speculate that other types of autoimmune diseases, evolving over a long period of time and in a manner similar to that described for GBS in the preceeding paragraph, may result from vaccinations.

A *second* item in S. 2117 which concerns me is that I read time after time in the list of covered injuries the word "acute." In my own experience, injury from a vaccine may be insidious, and greater recognition needs to be given to this point. I was never "acutely" ill. At no time was I paralyzed, unconscious, suffering from seizures, high fever, or pain. Yet, I suffer considerable disability because of the residual damage to my nervous system, which causes me to tire very easily to the point where I cannot function. I urge greater emphasis on *chronic* illness, and on sensory impairment or loss which may result from inoculations.

A *third* area in which I am uneasy about the provisions of S. 2117 is to absolve drug manufacturers of liability for the vaccine they produce. I understand your concern about the dramatic increase in the cost of vaccine, but I question enacting a law that allows drug manufacturers to make and distribute a vaccine without any liability for its safety. That, in my opinion, is one reason why so much of the swine flu vaccine was shot into people's arms without adequate testing and without proper safeguards for its purity. If I recall correctly, one provision of the Swine Flu Act was that the Government could sue the vaccine manufacturer if they believed the vaccine was defective. Proof that swine flu vaccine caused GBS was provided by experiments conducted in 1979-80 by Dr. T. M. Phillips and Dr. Edward Eylar. Monkeys inoculated with P-2 protein from the vaccine developed Experimental Allergic Neuritis (EAN), the animal equivalent of GBS. Yet, to my knowledge, the government has sued no drug manufacturer.

Fourth, I am concerned that claims by petitioners will be decided by the United States District Court for the District of Columbia. This arrangement, it seems to me, has the same potential for politicalization as having a federal judge be the sole decision maker in suits against the government under provisions of the Federal Tort Claims Act. In my opinion, the decision should be made by a panel from the public sector, of doctors, lawyers and vaccine victims.

Fifthly, I am concerned there is no provision to compensate victims of swine flu and other vaccines.

I realize that the premise of S. 2117 is to compensate victims of mandatory vaccines. However, a case can be made for those of us who took the vaccine in the belief it was our civic duty to help break the chain of contagion of a killer disease. So called "herd immunity" is the objective of any National immunization campaign. But a majority of the public must be willing to take the vaccine for this objective to be realized. As Robert Levine, chairman of Yale University's institutional review board and a professor of medicine states, "Even though it's voluntary, it still is in the interest of public health and the government." (Quoted from "Compensation for Victims of Vaccines," by Marjorie Hall, Science, Vol. 211, Feb, 1981).

Quoting from the bill (Section 2101, a, 4) "(4) because communicable disease is a national problem, because the primary thrust for vaccination has come from the Federal Government, and because vaccine-related injuries which may tend to undermine the public's confidence in vaccination programs are a national concern, there is a national need for, and responsibility to establish, a national vaccine-injury compensation program as a non-mandatory alternative to the current tort system."

Certainly the public's faith in government-sponsored vaccination programs has been tarnished. This lessening of confidence is unfortunate for we are always in eminent danger of a flu epidemic because of the antigenic shift in flu genes. Stephen H. Hall, writing in the November, 1983, issue of Science, comments: "The shuffling of flu genes can give the virus the genetic equivalent of five aces, creating a virulent hybrid."

I envision the scenario when the next flu epidemic threatens: the Government will give a vaccination program, and nobody will come.

A bill to justly compensate all vaccine victims would ignite the spark to rekindle Americans' confidence in the government's ability to provide for the public health.

Wilma Lundy

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April 19, 1984

Ms. Robin Rushton
Office of Senator Paula Hawkins
313 Hart
Washington, D.C. 20510

Dear Ms. Rushton:

I am writing you to elaborate on our telephone conversation yesterday. This past winter our daughter Kathryn contracted a fulminant case of paralytic polio after receiving one dose of the oral polio vaccine. Now two months later, at the age of five months, she still has continuing severe paralysis of both of her legs. Although this is a rare occurrence, it is an extremely real and horrifying one to those families affected by paralytic polio following the oral vaccine.

As you may know, there continues to be ten cases per year of vaccine-induced polio in this country, and there have been over two hundred cases since the oral live-virus vaccine became the vaccine in general use in this country in 1962. This is contrasted sadly with the Scandanavian countries of Finland and Sweden, which have had no reported cases of vaccine-induced or community acquired polio in over fifteen years with the use of the killed-virus vaccine.

We applaud your work and that of Senator Paula Hawkins with the National Childhood Vaccine-Injury Compensation Act. Increased public awareness of both the importance of complete vaccination and the nationwide responsibility for those injured by vaccines is crucial for preventing future widespread epidemics. Funding for improvement of vaccines and dissemination of informed consent about vaccines is essential. Please let us know if there is anything we can do to help bring this about. We will continue to be in touch with Dr. Jonas Salk and would be happy to testify on behalf of all those affected by the oral polio vaccine.

Sincerely yours,

Hadley Wilson

Hadley Wilson, M.D.
Department of Medicine
Vanderbilt University

cc: Senator Paula Hawkins
Senator Howard Baker
Senator James Sasser
Senator Jesse Helms
Senator John East
Representative William Boner
Representative Albert Gore
Representative James Broyhill

TURNING POINT
Family Wellness Center

Edward H. Chapman, M.D.
Dolores Heeb, Reg. Ac.
Richard P. Ingrasci, M.D., M.P.H.
Richard Moskowitz, M.D.
Geri Schumacher, R.N.

April 30, 1984

The Honorable Paula Hawkins
U. S. Senate
Washington, D. C.

Dear Senator Hawkins:

I am enclosing the following articles that I wrote in the hope that you and your Committee will consider them before making a final recommendation on the Bill to compensate injured victims of the DPT vaccine which is presently under study.

I understand that it is too late to come to testify in person. I would like if possible to have the enclosed articles published in the Congressional Record, so that the public may know that an alternative viewpoint exists and deserves to be taken seriously.

Thank you for your consideration.

Truly yours,

Richard Moskowitz

Richard Moskowitz, M. D.

173 Mt. Auburn Street, Watertown, Massachusetts 02172 (617) 923-4601

Reprinted from the Journal of the American Institute of Homoeopathy, 76: 7, March 1983.

THE CASE AGAINST IMMUNIZATIONS

By Richard Moskowitz, M.D.

For the past ten years or so, I have felt a deep and growing compunction against giving routine immunizations to children. It began with the fundamental belief that people have the right to make that choice for themselves. Soon I discovered that I could no longer bring myself to give the injections even when the parents wished me to.

At bottom, I have always felt that the attempt to eradicate entire microbial species from the biosphere must inevitably upset the balance of nature in fundamental ways that we can as yet scarcely imagine. Such concerns loom ever larger as new vaccines continue to be developed, seemingly for no better reason than that we have the technical capacity to make them, and thereby to demonstrate our power, as a civilization, to manipulate the evolutionary process itself.

Purely from the viewpoint of our own species, even if we could be sure that the vaccines were harmless, the fact remains that they are *compulsory*, that all children are required to undergo them, without any sensitive regard for basic differences in individual susceptibility, to say nothing of the wishes of the parents or the children themselves.

Most people can readily accept the fact that, from time to time, certain laws may be necessary for the public good that some of us strongly disagree with. But the issue in this case involves nothing less than the introduction of foreign proteins or even live viruses into the bloodstream of entire populations.

For that reason alone, the public is surely entitled to convincing proof, beyond any reasonable doubt, that artificial immunization is in fact a safe and effective procedure, in no way injurious to health, and that the threat of the corresponding natural diseases remains sufficiently clear and urgent to warrant mass inoculation of everyone, even against their will if necessary.

Unfortunately, such proof has never been given; and, even if it could be, continuing to employ vaccines against diseases that are no longer prevalent or no longer dangerous hardly qualifies as an emergency.

Finally, even if such an emergency did exist, and artificial immunization could be shown to be an appropriate response to it, the decision would remain essentially a *political* one, involving issues of public health and safety that are far too important to be settled by any purely scientific or technical criteria, or indeed by *any* criteria less authoritative than the clearly articulated sense of the community about to be subjected to it.

For all of these reasons, I want to present the case against routine immunization as clearly and forcefully as I can. What I have to say is not quite a formal theory capable of rigorous proof or disproof. It is simply an attempt to explain my own experience, a nexus of interrelated facts, observations, reflections, and hypotheses which, taken together, are more or less coherent and plausible and make intuitive sense to me.

I offer them to the public in part because the growing refusal of parents to vaccinate their children is so seldom articulated or taken seriously. The fact is that we have been taught to accept vaccination as a sort of involuntary communion, a sacrament of our own participation in the unrestricted growth of scientific and industrial technology, utterly heedless of the long-term consequences to the health of our own species, let alone to the balance of nature as a whole. For that reason alone, the other side of the case urgently needs to be heard.

1. ARE THE VACCINES EFFECTIVE?

There is widespread agreement that the time period since the common vaccines were introduced has seen a remarkable decline in the incidence and severity of the corresponding natural infections. But the customary assumption that the decline is *attributable* to the vaccines remains unproven, and continues to be seriously questioned by eminent authorities in the field. The incidence and severity of whooping cough, for example, had already begun to decline precipitously long before the pertussis vaccine was introduced (1), a fact which led the epidemiologist C. C. Dauer to remark, as far back as 1943:

> If mortality [from pertussis] continues to decline at the same rate during the next 15 years, it will be extremely difficult to show statistically that [pertussis immunization] had any effect in reducing mortality from whooping cough (2).

Much the same is true not only of diphtheria and tetanus, but also of TB, cholera, typhoid, and other common scourges of a bygone era, which began to disappear toward the end of the nineteenth century, perhaps partly in response to improvements in public health and sanitation, but in any case long before antibiotics, vaccines, or any specific medical measures designed to eradicate them (3).

Reflections such as these led the great microbiologist René Dubos to observe that microbial diseases have their own natural history, independent of drugs and vaccines, in which asymptomatic infection and symbiosis are far more common than overt disease:

> It is barely recognized, but nevertheless true, that animals and plants, as well as men, can live peacefully with their most notorious microbial enemies. The world is obsessed by the fact that poliomyelitis can kill and maim several thousand unfortunate victims every year. But more extraordinary is the fact that millions upon millions of young people become infected by polio viruses, yet suffer no harm from the infection. The dramatic episodes of conflict between men and microbes are what strike the mind. What is less readily apprehended is the more common fact that infection can occur without producing disease (4).

The principal evidence that the vaccines are effective actually dates from the more recent period, during which time the dreaded polio epidemics of the 1940's and 1950's have never reappeared in the developed countries, and measles, mumps, and rubella, which even a generation ago were among the commonest diseases of childhood, have become far less prevalent, at least in their classic acute forms, since the triple MMR vaccine was introduced into common use.

Yet how the vaccines actually accomplish these changes is not nearly as well understood as most people like to think it is. The disturbing possibility that they act in some other way than by producing a genuine immunity is suggested by the fact that the diseases in question have continued to break out even in highly immunized populations, and that in such cases the observed differences in incidence and severity between immunized and unimmunized persons have tended to be far less dramatic than expected, and in some cases not measurably significant at all.

In a recent British outbreak of whooping cough, for example, even fully immunized children contracted the disease in fairly large numbers, and the rates of serious complications and death were reduced only slightly (5). In another recent outbreak of pertussis, 46 of the 85 fully immunized children studied eventually contracted the disease (6).

In 1977, 34 new cases of measles were reported on the campus of UCLA, in a population that was supposedly 91 percent immune, according to careful serological testing (7). Another 20 cases of measles were reported in the Pecos, New Mexico area within a period of a few months in 1981, and 75 percent of them had been fully immunized, some of them quite recently (8). A survey of sixth-graders in a well-immunized urban community revealed that about 15 percent of this age group are still susceptible to rubella, a figure essentially identical with that of the pre-vaccine era (9).

Finally, although the overall incidence of typical acute measles in the U.S. has dropped sharply from about 400,000 cases annually in the early 1960's to about 30,000 cases by 1974–76, the death rate remained exactly the same (10); and, with the peak incidence now occurring in adolescents and young adults, the risk of pneumonia and demonstrable liver abnormalities has actually increased substantially, according to one recent study, to well over 3 percent and 2 percent, respectively (11).

The simplest way to explain these discrepancies would be to postulate that the vaccines confer only partial or temporary immunity, which sounds reasonable enough, given the fact that they are either live viruses rendered less virulent by serial passage in tissue culture, or bacteria or bacterial proteins that have been killed or denatured by heat, such that they can still elicit an antibody response but no longer initiate the full-blown disease.

Because the vaccine is a "trick," in the sense that it *simulates* the true or natural immune response developed in the course of recovering from the actual disease, it is certainly realistic to expect that such artificial immunity will in fact "wear off" quite easily, and even require additional "booster" doses at regular intervals throughout life to maintain peak effectiveness.

Such an explanation would be disturbing enough for most people. Indeed, the basic fallacy inherent in it is painfully evident in the fact that there is no way to know how long this partial or temporary immunity will last in any given individual, or how often it will need to be restimulated, because the answers to these questions clearly depend on precisely the same individual variables that would have determined whether or how severely the same person, unvaccinated, would have contracted the disease in the first place.

In any case, a number of other observations suggest equally strongly that this simple explanation cannot be the correct one. In the first place, a number of investigators have shown that when a person vaccinated against the measles, for example, again becomes susceptible to it, even repeated booster doses will have little or no effect (12).

In the second place, the vaccines do not act merely by producing pale or mild copies of the original disease; all of them also commonly produce a variety of symptoms of their own. Moreover, in some cases, these illnesses may be considerably more serious than the original disease, involving deeper structures, more vital organs, and less of a tendency to resolve spontaneously. Even more worrisome is the fact that they are almost always more difficult to recognize.

Thus, in a recent outbreak of mumps in supposedly immune school-children, several developed atypical symptoms, such as anorexia, vomiting, and erythematous rashes, without any parotid involvement, and the diagnosis required extensive serological testing to rule out other concurrent diseases (13). The snydrome of "atypical measles" can be equally difficult to diagnose, even when it is thought of (14), which suggests that it is often overlooked entirely. In some cases, atypical measles can be much more severe than the regular kind, with pneumonia, petechiae, edema, and severe pain (15), and likewise often goes unsuspected.

In any case, it seems virtually certain that other vaccine-related syndromes will be described and identified, if only we take the trouble to look for them, and that the ones we are aware of so far represent only a very small part of the problem. But even these few make it less and less plausible to assume that the vaccines produce a normal, healthy immunity that lasts for some time but then *wears off*, leaving the patient miraculously unharmed and unaffected by the experience.

2. SOME PERSONAL EXPERIENCES WITH VACCINE-RELATED ILLNESS.

I would like now to present a few of my own vaccine cases, both to give a sense of their variety and chronicity, and to show how difficult it can be to trace them, and also to begin to address the crucial question that is too seldom even asked, namely, how the vaccines actually *work*, i.e. what effects they do in fact produce in the human body.

> My first case was that of an 8-month-old girl with recurrent fevers of unknown origin. I first saw here in January of 1977, a few weeks after her third such episode. These were brief, lasting 48 hours at most, but very intense, with the fever typically reaching 105° F. During the second episode, she was hospitalized for diagnostic evaluation, but her pediatrician found nothing out of the ordinary. Apart from these episodes, the child felt quite well, and appeared to be growing and developing normally.
>
> I could get no further information from the mother, except for the fact that the episodes had occurred almost exactly one month

> apart; and, upon consulting her calendar, we learned that the first episode had come exactly one month after the last of her DPT injections, which had also been given at monthly intervals. At this point, the mother remembered that the child had had similar febrile episodes immediately after each injection, but that she had been instructed to ignore them, inasmuch as they are "common reactions" to the vaccine. I therefore gave the child a single *oral* dose of dilute homoeopathic DPT vaccine; and I am happy to report that the child has remained well since, with no further episodes of any kind.

This case illustrates how homoeopathic remedies prepared from vaccines can be used for *diagnosis* as well as treatment of vaccine-related illnesses, which, no matter how strongly they are suspected, might otherwise be almost impossible to substantiate.

Secondly, because fever is the commonest known complication of the pertussis vaccine, and inasmuch as the child seemed quite well between the attacks, her response to the vaccine appeared to be a relatively strong and healthy one, disturbing because of its recurrence and periodicity, but in any case relatively simple to cure, as indeed it proved to be. But one cannot help wondering what happens to the vaccine in those tens of millions of children who show no obvious response to it at all.

Since that time, I have seen at least half a dozen cases of children with recurrent fevers of unknown origin, associated with a variety of other chronic complaints, chiefly irritability, temper tantrums, and increased susceptibility to colds, tonsillitis, and ear infections, which were similarly traceable to the pertussis vaccine, and which responded successfully to treatment with the homoeopathic DPT nosode. Indeed, I would have to say, on the basis of that experience, that the pertussis vaccine is probably one of the major causes of recurrent fevers of unknown origin in small children today.

> My second case was that of a 9½-month-old girl, who presented acutely with a fever of 105° F., and very few other symptoms. Like the first, this child had had two similar episodes previously, but at irregular intervals; and the parents, who felt ambivalent about vaccinations in general, had given her only one dose of the DPT vaccine so far, although the first episode occurred a few weeks afterwards.
>
> I first saw the child in June of 1978. The fever remained high and unremitting for 48 hours, despite the usual acute remedies and supportive measures. A CBC revealed a white count of 32,100 per cu. mm., with 43 percent lymphocytes, 11 percent monocytes, 25 percent neutrophils (many with toxic granulations), 20 percent bands (also with toxic granulations), and 1 percent metamyelocytes and other immature forms. When I asked a pediatrician about these findings, "pertussis" was his immediate reply. After a single oral dose of homoeopathic DPT vaccine, the fever came down abruptly within a few hours, and the child has remained well since.

This case was disturbing mainly because of the hematological abnormalities, which were in the leukemoid range, together with the absence of any cough or distinctive respiratory symptoms, which suggested that introducing the vaccine directly into the blood may actually promote deeper or more systemic pathology than allowing the pertussis organism to set up typical symptoms of local inflammation at the normal portal of entry.

> The third case was a 5-year-old boy with chronic lymphocytic leukemia, whom I happened to see in August of 1978, while visiting an old friend and teacher, a family physician with over 40 years' experience. Well out of earshot of either the boy or his parents, he told me that the leukemia had first appeared following a DPT vaccination, and that, although he had treated the child successfully with natural remedies on two previous occasions, with shrinking of the liver and spleen to approximately normal size, and dramatic improvement in the blood picture, full relapse had occurred soon after each successive DPT booster.

The idea that vaccinations might also be implicated in some cases of childhood leukemia was shocking enough in itself, but it also completed the line of reasoning opened up by the previous case. For leukemia is a cancerous process of the blood and the blood-forming organs, the living, the spleen, the lymph nodes, and the bone marrow, which are also the basic anatomical units of the immune system. Insofar as the vaccines are capable of producing serious complications at all, the blood and the immune organs would certainly be the logical place to begin looking for them.

But perhaps even more shocking to me is the fact that the boy's own physician dared not communicate his suspicion of vaccine-related illness to the parents, let alone to the general public. It was this case that convinced me, once and for all, of the need for serious, public discussion of our collected experiences with vaccine-related illness, precisely because rigorous experimental proof will require years of investigation and a firm public commitment that has not even been made yet.

I will now present two cases from my limited experience with MMR vaccine.

> In December of 1980 I saw a 3-year-old boy with a 4-week history of loss of appetite, stomach aches, indigestion, and swollen glands. The stomach pains were quite severe, and often accompanied by belching, flatulence, and explosive diarrhea. The nose was also congested, and the lower eyelids were quite red. The mother also reported some unusual behavior changes, such as extreme untidiness, "wild" and "noisy" playing, and waking at 2 a.m. to get into bed with the parents.
>
> The physical examination was unremarkable except for some large, tender left posterior auricular and suboccipital nodes, and marked enlargement of the tonsils. I then learned that the child had received the MMR vaccine in October, about 2 weeks before the onset of symptoms, with no apparent reaction to it at the time. I gave the child a single dose of the homoeopathic rubella vaccine, and the symptoms promptly disappeared within 48 hours.
>
> In April 1981, the parents brought him back for a slight fever, and another 3-week history of intermittent pain in and behind the right ear, stuffy nose, etc. On examination, the whole right side of the face appeared to be swollen, especially the cheek and the angle of the jaw. The right eye was red and injected. He responded well to acute homoeopathic remedies, and has remained well since.

This boy was typical of my rubella vaccine cases. At an interval of a few weeks after the MMR vaccine, which is about the same as the normal incubation period of rubella, a rather nondescript illness develops, which becomes subacute and rather more severe than rubella in the same age group, with, e.g., abdominal or joint pains and marked adenopathy, but no rash. Usually the diagnosis is suspected because of the characteristic posterior auricular and suboccipital nodes, and confirmed by a favorable response to the homoeopathic rubella nosode.

As I read over this case, I am struck by the posssibility that his second illness, and especially the parotid enlargement, may have represented continuing activity of the mumps component of the vaccine, inasmuch as I did not have the triple MMR nosode, but only those derived from the individual components. We must therefore also consider the probability that a variety of "mixed" or composite syndromes may occur, representing the patient's responses to two or all three of the vaccine components, either simultaneously or over time.

> In April of 1981 I first saw a 4-year-old boy for bilateral chronic enlargement of the posterior auricular nodes, which were also occasionally tender. The mother had noticed the swelling for about one year, during which time he had become more susceptible to various upper respiratory infections, none of them especially severe. The mother had also noticed recurrent parotid swelling at irregular intervals over the same time period, which began shortly after the MMR vaccine was given at the age of 3.
>
> At the time of the first visit, the child was not ill; and, because the mother was about 2 months pregnant at the time, I elected to observe the child and do nothing if possible until the pregnancy was over. He did develop a mild laryngitis in the last trimester, which responded well to bed rest and simple homoeopathic remedies.
>
> In April of 1982, he came down with acute bronchitis. I noticed that the posterior auricular nodes were once again swollen and tender, and I decided to give him the homoeopathic rubella nosode at that point. The cough promptly subsided, and the nodes regressed in size and were no longer tender. Two weeks later, however, he returned with a noticeably hard, tender swelling on the outside of the right cheek, near the angle of the jaw, and some pain on chewing or opening the mouth. A single dose of the homoeopathic mumps nosode was given, and the child has been well since.

In this case also, we see the subacute pattern of the disease, with a strong tendency to chronicity and increased susceptibility to weaker, low-grade responses, in contrast to the vigorous, acute responses typically associated with diseases like the measles and the mumps when acquired naturally.

3. HOW DO THE VACCINES WORK?

It is dangerously misleading, and, indeed, the exact opposite of the truth to claim that a vaccine makes us "immune" or *protects* us against an acute disease, if in fact it only drives the disease deeper into the interior and causes us to harbor it *chronically*, with the result that our responses to it become progressively weaker, and show less and less tendency to heal or resolve themselves spontaneously.

What i propose, then, is simply to investigate as thoroughly and objectively as we can how the vaccines actually *work* inside the human body, and to begin by paying attention to the implications of what we already know. In particular, I would like to consider in detail the process of falling ill with and recovering from a typical acute disease, such as the measles, in contrast with what we can observe following the administration of the measles vaccine.

We all know that measles is primarily a virus of the respiratory tract, both because it is inhaled by susceptible persons upon contact with infected droplets in the air, and because these droplets are produced by the coughing and sneezing of a person with the disease.

Once inhaled by a susceptible person, the measles virus then undergoes a long period of silent multiplication, first in the tonsils, adenoids, and accessory lymphoid tissues of the nasopharynx; later in the regional lymph nodes of the head and neck; and eventually, several days later, it passes into the blood and enters the spleen, the liver, the thymus, and the bone marrow, the "visceral" organs of the immune system (16). Throughout this "incubation" period, which lasts from 10 to 14 days, the patient usually feels quite well, and experiences few or no symptoms (17).

By the time that the first symptoms of measles appear, circulating antibodies are already detectable in the blood, and the height of the symptomatology coincides with the peak of the antibody response (18). In other words, the "illness" is simply the definitive effort of the immune system to clear the virus from the blood. Equally noteworthy is the fact that the virus is eliminated by sneezing and coughing, i.e., via the same route through which it entered in the first place.

It is evident that the process of *mounting* an acute illness like the measles, no less than recovering from it, involves a general mobilization of the entire immune system, including inflammation of the previously sensitized tissues at the portal of entry, activation of leukocytes and macrophages, liberation of the serum complement system, and a host of other mechanisms, of which the production of circulating antibody is only one, and by no means the most important.

Such a splendid outpouring leaves little doubt that such illnesses are in fact the decisive experiences in the normal physiologic maturation of the immune system as a whole in the life of a healthy child. For not only will the child who recovers from the measles never again be susceptible to it (19); such an experience also cannot fail to prepare the individual to respond even more promptly and effectively to any infections he may acquire in the future. The ability to mount a vigorous acute response to organisms of this type must therefore be reckkoned among the most fundamental requirements of general health and well-being.

In contrast, when an artificially attenuated virus such as measles is injected directly into the blood, by-passing the normal portal of entry, at most a brief inflammatory reaction may be noted at the injection site, or in the regional lymph nodes; but there is no "incubation period" of local contact at the normal portal of entry, and consequently very little possibility of eliminating the virus via the same route.

Even more important is the fact that the virus has been artificially "attenuated," so that it will no longer initiate a generalized inflammatory response, or indeed any of the nonspecific defense mechanisms that help us to respond to infection generally. By "tricking" the body in this fashion, we have accomplished what the entire immune system seems to have evolved in order to prevent: we have placed the virus directly into the blood, and given it free and immediate access to the major immune organs and tissues, without any obvious way of getting rid of it.

The result is, indeed, the production of circulating antibodies against the virus, which can be measured in the blood; but the antibody response now occurs as an isolated technical feat, without any generalized inflammatory response, or any noticeable improvement in the general health of the organism. Exactly the opposite, in fact: the price that we have to pay for those antibodies is the persistence of virus elements in the blood for prolonged periods of time, perhaps permanently, which in turn presupposes a systematic weakening of our ability to mount an effective response not only to measles, but also to other acute infections as well.

Far from producing a genuine immunity, then, the vaccines may act by actually interfering with or *suppressing* the immune response as a whole, in much the same way that radiation, chemotherapy, and corticosteroids and other anti-inflammatory drugs do. Artificial immunization focuses on *antibody production*, a single aspect of the immune process, and disarticulates it and allows it to stand for the whole, in much the same way as chemical suppression of an elevated blood pressure is accepted as a valid substitute for a genuine *cure* of the patient whose blood pressure has risen. Worst of all, by making it difficult or impossible to mount a vigorous, acute response to infection, artificial immunization substitutes for it a much weaker, *chronic* response, with little or no tendency to heal itself spontaneously.

Moreover, adequate models already exist for predicting and explaining what sorts of chronic disease are likely to result from the chronic, long-term persistence of viruses and other foreign proteins within the cells of the immune system. It has long been known that live viruses, for example, are capable of surviving or remaining latent within the host cells for years, without continually provoking acute disease. They do so simply by attaching their own genetic material as an extra particle or "episome" to the genome of the host cell, and replicating along with it, which allows the host cell to continue its own normal functions for the most part, but imposes on it additional instructions for the synthesis of viral proteins (20).

Latent viruses of this type have already been implicated in three distinct types of chronic disease, namely, 1) *recurrent or episodic acute diseases*, such as herpes, shingles, warts, etc. (21); 2) *"slow-virus" diseases*, i.e., subacute or chronic, progressive, often fatal conditions, such as kuru, Creuzfeldt-Jakob disease, subacute sclerosing panencephalitis (SSPE), and possibly Guillain-Barre syndrome (22); and 3) *tumors*, both benign and malignant (23).

In any case, the latent virus survives as a clearly "foreign" element within the cell, which means that the immune system must continue to try to make antibodies against it, insofar as it can still respond to it at all. Because the virus is now permanently incorporated within the genetic material of the cell, these antibodies will now have to be directed against the cell itself.

The persistence of live viruses or other foreign antigens within the cells of the host therefore cannot fail to provoke *auto-immune* phenomena, because destroying the infected cells is now the only possible way that this constant antigenic challenge can be removed from the body. Since routine vaccination introduces live viruses and other highly antigenic material into the blood of virtually every living person, it is difficult to escape the conclusion that a significant harvest of auto-immune diseases most automatically result.

Sir Macfarlane Burnet has observed that the components of the immune system all function as if they were collectively designed to help the organism to discriminate "self" from "non-self," i.e., to help us to recognize and tolerate our own cells, and to identify and eliminate foreign or extraneous substances as completely as possible (24). This concept is exemplified not only by the acute response to infection, but also by the rejection of transplanted tissues, or "homografts," both of which result in the complete and permanent removal of the offending substance from the body.

If Burnet is correct, then latent viruses, auto-immune phenomena, and cancer would seem to represent different aspects of the same basic dilemma, which the immune system can neither escape nor resolve. For all of them presuppose a certain degree of *chronic immune failure*, a state in which it becomes difficult or impossible for the body either to recognize its own cells as unambiguously its own, or to eliminate its parasites as unequivocally foreign.

In the case of the attenuated measles virus, it is not difficult to imagine that introducing it directly into the blood would continue to provoke an antibody response for a considerable period of time, which is doubtless the whole point of giving the vaccine; but that eventually, as the virus succeeded in attaining a state of latency within the cell, the antibody response would wane, both because circulating antibodies cannot normally cross the cell membrane, and because they are also powerful immunosuppressive agents in their own right (25).

The effect of circulating antibody will thereafter be mainly to keep the virus *within* the cell, i.e., to continue to prevent any acute inflammatory response, until eventually, perhaps under circumstances of accumulated stress or emergency, this precarious balance breaks down, antibodies begin to be produced in large quantities against the cells themselves, and frank auto-immune phenomena of necrosis and tissue destruction supervene. Latent viruses, in this sense, are like biological "time bombs," set to explode at an indeterminate time in the future (26).

Auto-immune diseases have always seemed obscure, aberrant, and bizarre, because it is not intuitively obvious why the body should suddenly begin to attack and destroy its own tissues. They make a lot more sense, and, indeed, must be reckoned as "healthy," if destroying the chronically infected cells is the only possible way of eliminating an even more serious threat to life, namely, the persistence of the foreign antigenic challenge within the cells of the host.

Tumor formation could then be understood as simply a more advanced stage of chronic immune failure, according to the same model. For, as long as the host is subjected to enormous and unremitting pressure to make antibodies against itself, that response will automatically tend to become less and less effective.

Eventually, under stress of this magnitude, the auto-immune mechanism could easily break down to the point that the chronically infected and genetically transformed cells, no longer clearly "self" or "non-self," begin to free themselves from the normal restraints of "histocompatibility" within the architecture of the surrounding cells, and begin to multiply autonomously at their expense.

A tumor could then be described as "benign" insofar as the breakdown of histocompatibility remains strictly localized to the tissue of origin, and "malignant" insofar as it begins to spread to other cell types, tissues, and organs, even in more remote areas. Malignancy might simply represent the reactivation of the virus from its latent phase into a more acute mode, albeit with less inflammation and more tissue destruction than the original wild-type infection.

If what I am saying turns out to be true, then what we have done by artificial immunization is essentially to trade off our acute, epidemic diseases of the past century for the weaker and far less curable chronic diseases of the present, with their amortizable suffering and disability. In doing so, we have also opened up limitless evolutionary possibilities for the future of ongoing *in vivo* genetic recombination within the cells of the race.

4. THE INDIVIDUAL VACCINES RECONSIDERED.

I want next to consider each of the vaccines on an individual basis, in relation to the infectious diseases from which they are derived.

The MMR is composed of attenuated live measles, mumps, and rubella viruses, administered in a single intramuscular injection at about 15 months of age. Subsequent re-immunization is no longer recommended, except for young women of childbearing age, in whom the risk of congenital rubella syndrome (CRS) is thought to warrant it, even though the effectiveness of re-immunization is questionable at best.

Prior to the vaccine era, measles, mumps, and rubella were reckoned among the "routine childhood diseases," which most school-children contracted before the age of puberty, and from which nearly all recovered, with permanent, lifelong immunity, and no complications or sequelae.

But they were not always so harmless. Measles, in particular, can be a devastating disease when a population encounters it for the first time. Its importation from Spain, for instance, undoubtedly contributed to Cortez' conquest of the great Aztec Empire: whole villages were carried off by epidemics of measles and smallpox, leaving only a small remnant of cowed, superstitious warriors to face the bearded *conquistadores* from across the sea (27). In more recent outbreaks among isolated, primitive peoples, the case fatality rate from measles averaged 20 to 30 percent (28).

In both these so-called "virgin-soil" epidemics, not only measles but also polio and many other similar diseases take their highest toll of death and serious complications among adolescents and young adults, healthy and vigorous people in the prime of life, and leave relatively unharmed the group of school-age children before the age of puberty (29).

This means that the evolution of a disease such as measles from a dreaded killer to an ordinary disease of childhood presupposes the development of nonspecific or "herd" immunity in young children, such that, when they are finally exposed to the disease, it activates defense mechanisms already prepared and in place, resulting in the long incubation period and the usually benign, self-limited course described above.

Under these circumstances, the rationale for wanting to vaccinate young children against measles is limited to the fact that a very small number of deaths and serious complications have continued to occur, chiefly pneumonia, encephalitis, and the rare but dreaded subacute sclerosing panencephalitis (SSPE), a slow-virus disease with a reported incidence of 1 per 100,000 cases (30). Pneumonia, by far the commonest complication, is usually benign and self-limited, even without treatment (31); and, even in those rare cases in which bacterial pneumonia supervenes, adequate treatment is currently available.

By all accounts, then, the death rate from wild-type measles is very low, the incidence of serious sequelae is insignificant, and the general benefit to the child who recovers from the disease, and to his contacts and descendants, is very great. Consequently, even if the measles vaccine could be shown to reduce the risk of death or serious complications from the disease, it still could not justify the high probability of auto-immune diseases, cancer, and whatever else may result from the propagation of latent measles virus in human tissue culture for life.

Ironically, what the measles vaccine certainly has done is to reverse the historical or evolutionary process to the extent that measles is once again a disease of adolescents and young adults (32), with a correspondingly higher incidence of pneumonia and other complications, and a general tendency to be a more serious and disabling disease than it usually is in younger children.

As for the claim that the vaccine has helped to eliminate measles encephalitis, I myself, in my own relatively small general practice, have already seen two children with major seizure disorders which the parents clearly ascribed to the measles vaccine, although they would never have been able to prove the connection in a court of law, and never even considered the possibility of compensation.

Such cases therefore never make the official statistics, and are accordingly omitted from conventional surveys of the problem. Merely injecting the virus into the blood would naturally favor a higher incidence of deep or visceral complications affecting the lungs, liver, and brain, for which the measles virus has a known affinity.

The case for immunizing against mumps and rubella seems *a fortiori* even more tenuous, for exactly the same reasons. Mumps is also essentially a benign, self-limited disease in children before the age of puberty, and recovery from a single attack confers lifelong immunity. The principal complication is meningoencephalitis, mild or subclinical forms of which are relatively common, although the death rate is extremely low (33), and sequelae are rare.

The mumps vaccine is prepared and administered in much the same way as the measles, usually in the same injection; and the dangers associated with it are likewise comparable. Again like the measles, mumps too is fast becoming a disease of adolescents and young adults (34), age groups which tolerate the disease much less well. The chief complication is acute epididymo-orchitis, which occurs in 30 to 40 percent of the males affected past the age of puberty, and usually results in atrophy of the testicle on the affected side (35); but it also shows a strong tendency to attack the ovary and the pancreas.

For all of these reasons, the greatest favor we could do for our children would be to expose them all to the measles and mumps when they are young, which would not only protect them against contracting more serious forms of these diseases when they grow older, but would also greatly assist in their immunological maturation with minimal risk. I need hardly add that this is very close to the actual evolution of these diseases before the MMR vaccine was introduced.

The same discrepancy is evident in the case of rubella, or "German measles," which in young children is a disease so mild that it frequently escapes detection (36), but in older children and adults not infrequently produces arthritis, purpura, and other severe, systemic signs (37). The main impetus for the development of the vaccine was certainly the recognition of the "congenital rubella syndrome (CRS)," resulting from damage to the developing embryo *in utero* during the first trimester of pregnancy (38), and the relatively high incidence of CRS traceable to the rubella outbreak of 1964.

But here again, we have an almost entirely benign, self-limited disease transformed by the vaccine into a considerably less benign disease of adolescents and young adults of reproductive age, which is, ironically, the group that most needs to be protected against it. Moreover, as with measles and mumps, the simplest and most effective way to prevent CRS would be to expose everybody to rubella in elementary school; re-infection does sometimes occur after recovery from rubella, but much less commonly than after vaccination (39).

The equation looks somewhat different for the diphtheria and tetanus vaccines. First of all, both diphtheria and tetanus are serious, sometimes fatal diseases, even under the best of treatment; this is especially true of tetanus, which still carries a mortality of close to 50 percent.

Furthermore, these vaccines are not made from living diphtheria and tetanus organisms, but only from certain "toxins" elaborated by them; these poisonous substances are still highly antigenic, even after being inactivated by heat. Diphtheria and tetanus "toxoids" therefore do not protect against infection *per se*, but only against the systemic action of the original poisons, in the absence of which both infections are of minor importance clinically.

Consequently, it is easy to understand why parents might want their children protected against diphtheria and tetanus, if safe and effective protection were available. Moreover, both vaccines have been in use for a long time, and the reported incidence of serious problems has remained very low, so that there has never been much public outcry against them.

On the other hand, both diseases are quite readily controlled by simple sanitary measures and careful attention to wound hygiene; and, in any case, both have been steadily disappearing from the developing countries, since long before the vaccines were introduced.

Diphtheria now occurs sporadically in the United States, often in areas with significant reservoirs of unvaccinated children. But the claim that the vaccine is "protective" is once again belied by the fact that, when the disease does break out, the supposedly "susceptible" children are in fact no more likely to develop clinical diphtheria than their fully immunized contacts. In a 1969 outbreak in Chicago, for example, the Board of Health reported that 25 percent of the cases had been fully immunized, and that another 12 percent had received one or more doses of the vaccine and showed serological evidence of full immunity; another 18 percent had been partly immunized, according to the same criteria (40).

So, once again, we are faced with the probability that what the diphtheria toxoid has produced is not a genuine immunity to diphtheria at all, but rather some sort of chronic immune *tolerance* to it, by harboring highly antigenic residues somewhere within the cells of the immune system, presumably with long-term suppressive effects on the immune mechanism generally.

This suspicion is further aggravated by the fact that all of the DPT vaccines are alum-precipitated and preserved with Thiomersal, an organomercury derivative, to prevent them from being metabolized too rapidly, so that the antigenic challenge will continue for as long as possible. The fact is that we do not know and have never even attempted to discover what actually becomes of these foreign substances, once they are inside the human body.

Exactly the same problems complicate the record of the tetanus vaccine, which almost certainly has had at least some impact in reducing the incidence of tetanus in its classic acute form, yet presumably also survives for years or even decades as a potent foreign antigen within the body, with long-term effects on the immune system and elsewhere that are literally incalculable.

"Whooping cough," much like diphtheria and tetanus, began to decline as a serious epidemiological threat long before the vaccine was introduced. Moreover, the vaccine has not been particularly effective, even according to its proponents; and the incidence of known side-effects is disturbingly high.

The power of the pertussis vaccine to damage the central nervous system, for example, has received growing attention since Stewart and his colleagues reported an alarmingly high incidence of encephalopathy and severe convulsive disorders in British children that were traceable to the vaccine (41). My own cases, a few of which were reported above, suggest that hematological disturbances may be even more prevalent, and that, in any case, the *known* complications almost certainly represent a small fraction of the total.

In any case, the pertussis vaccine has become controversial even in the United States, where medical opinion has remained almost unanimous in favor of immunizations generally; and several countries, such as West Germany, have discontinued routine pertussis vaccination entirely (42).

Pertussis is also extremely variable clinically, ranging in severity from asymptomatic, mild, or inapparent infections, which are quite common actually, to very rare cases in young infants less than 5 months of age, in whom the mortality is said to reach 40 percent (43). Indeed, the disease is rarely fatal or even that serious in children over a year old, and antibiotics have very little to do with the outcome (44).

A good deal of the pressure to immunize at the present time thus seems to be attributable to the higher death rate in very young infants, which has led to the terrifying practice of giving this most clearly dangerous of the vaccines to infants at 2 months of age, when their mothers' milk would normally have protected them from all infections about as well as it can ever be done (45), and the effect on the still developing blood and nervous system could be catastrophic.

For all of these reasons, the practice of routine pertussis immunization should be discontinued as quickly as possible, and more studies done to assess and compensate the damage that it has already done.

Poliomyelitis and the polio vaccines present an entirely different situation. The standard Sabin vaccine is trivalent, consisting of attenuated, live polioviruses of each of the three strains associated with poliomyelitis; but it is administered orally, in much the same way as the infection is acquired in nature. The oral or non-injectable route, which leaves the recipient free to develop a natural immunity at the normal portal of entry, i.e., the GI tract, would therefore appear to represent a considerable safety factor.

On the other hand, the wild-type poliovirus produces no symptoms whatsoever in other 90 percent of the people who contact it, even under epidemic conditions (46); and, of those people who do come down with recognizable clinical disease, perhaps only 1 or 2 percent ever progress to the full-blown neurological picture of "poliomyelitis," with its characteristic lesions in the anterior horn cells of the spinal cord or medulla oblongata (47).

Poliomyelitis thus presupposes peculiar conditions of susceptibility in the host, even a specific *anatomical* susceptibility, since, even under epidemic conditions, the virulence of the poliovirus is so low, and the number of cases resulting in death or permanent disability was always remarkably small (48).

Given the fact that the poliovirus was unbiquitous before the vaccine was introduced, and could be found routinely in samples of city sewage wherever it was looked for (49), it is evident that effective, natural immunity to poliovirus was already as close to being universal as it can ever be, and *a fortiori* no artificial substitute could ever equal or even approximate that result. Indeed, because the virulence of the poliovirus was so low to begin with, it is difficult to see what further attenuation of it could possibly accomplish, other than to abate as well the full vigor of the natural immune response to it.

For the fact remains that even the attenuated virus is still alive, and the people who were anatomically susceptible to it before are still susceptible to it now. This means, of course, that at least *some* of these same people will develop paralytic polio from the vaccine (50), and that the others may still be harboring the virus in latent form, perhaps within those same cells.

The only obvious advantage of giving the vaccine, then, would be to introduce the population to the virus when they are still infants, and the virulence is normally lowest anyway (51); and even this benefit could be more than offset by the danger of weakening the immune response, as we have seen. In any case, the whole matter is clearly one of enormous complexity, and illustrates only too well the hidden dangers and miscalculations that are inherent in the virtually irresistible attempt to beat nature at her own game, to eliminate a problem that cannot be eliminated, i.e., the susceptibility to disease itself.

So even in the case of the polio vaccine, which appears to be about as safe as any vaccine ever *can* be, the same fundamental dilemma remains. Perhaps the day will come when we can face the consequences of deliberately feeding live polioviruses to every living infant, and admit that we should have left well enough alone, and addressed ourselves to the art of healing the sick when we have to, rather than to the technology of eradicating the *possibility* of sickness, when we don't have to, and can't possibly succeed in any case.

5. VACCINATION AND THE PATH OF MEDICAL TECHNOLOGY.

In conclusion, I want to go back to the beginning, to the essentially political aspects of vaccination, that oblige us all to reason and deliberate together about matters of common concern, and to reach a clear decision about how we choose to live. I have stated my own views regarding the safety and effectiveness of the vaccines, and I hope that others of differing views will do the same.

That is why I am deeply troubled by the atmosphere of fanaticism with which the vaccines are imposed on the public, and serious discussion of them is ignored or stifled by the medical authorities, as if the question had already been settled definitively and for all time. In the words of Sir Macfarlane Burnet,

> It is our pride that in a civilized country the only infectious diseases which anyone is likely to suffer are either trivial or easily cured by available drugs. The diseases that killed in the past have in one way or another been rendered impotent, and, in the process, general principles of control have been developed which should be applicable to any unexpected outbreak in the future (52).

Quite apart from the truth of these claims, they exemplify the smugness and self-righteousness of a profession and a society that worships its own ability to manipulate and control the processes of nature itself. That is why, as Robert Mendelsohn has said, "we are quick to pull the trigger, but slow to examine the consequences of our actions (53)."

Indeed, one would have to say, *methodically* slow. In 1978, for example, the American Academy of Pediatrics, which had been charged by Congress with responsibility to formulate guidelines for Federal compensation of "vaccination-related injuries," issued the following eligibility restrictions:

> 1. Compensation should be made available to any child or young person under the age of 18 years, or a contact of such person of any age, who suffers a major reaction to a vaccine mandated for school entry or continuation in school in his or her state of residence.
> 2. *Such a reaction should have been previously recognized as a possible consequence of the vaccine given.*
> 3. *Such a reaction should have occurred no more than 30 days following the immunization* (54).

These restrictions would automatically exclude all of the chronic diseases, or indeed anything other than the very few adverse reactions that have so far been identified, which clearly represent only a tiny fraction of the problem.

Still less can either the government or the medical establishment be considered ignorant of the possibility that lurks in every parent's mind and heart, namely, that the vaccines cause cancer and other chronic diseases. Precisely that possibility was raised by Prof. Robert Simpson of Rutgers in a 1976 seminar for science writers sponsored by the American Cancer Society:

> Immunization programs against flu, measles, mumps, polio, and so forth, may actually be seeding humans with RNA to form latent proviruses in cells throughout the body. These latent proviruses could be molecules in search of diseases; when activated, under proper conditions, they could cause a variety of diseases, including rheumatoid arthritis, multiple sclerosis, systemic lupus erythematosus, Parkinson's disease, and perhaps cancer (55).

Unfortunately, this is the sort of warning that very few people are willing or able to hear at this point, least of all the American Cancer Society or the American Academy of Pediatrics. The fact is, as Dubos points out, that all of us still want to believe in the "miracle," regardless of the evidence.

> The faith in the magical power of drugs often blunts the critical senses, and comes close at times to a mass hysteria, involving scientists and laymen alike. Men want miracles as much today as in the past. If they do not join one of the newer cults, they satisfy this need by worshiping at the altar of modern science. This faith in the magical power of drugs is not new. It helped to give medicine the authority of a priesthood, and to recreate the glamor of ancient mysteries (50).

The idea of eradicating measles or polio has come to seem attractive to us simply because the power of medical science makes it seem technically *possible*: we worship every victory of technology over nature, just as the bullfight celebrates the triumph of human intelligence over the brute beast.

That is why we do not begrudge the drug companies their enormous profits and gladly volunteer our own bodies and those of our children for their latest experiments. Vaccination is essentially a religious sacrament of our own participation in the miracle, a veritable *auto-da-fé* in the name of modern civilization itself.

Nobody in his right mind would seriously entertain the idea that, if we could somehow eliminate, one by one, measles and polio and all the known diseases of mankind, we would be any the healthier for it, or that other even more serious diseases would not quickly take their place.

Still less would a rational being suppose that the illnesses from which he suffered were "entities" somehow separable from the patients who suffer them, and that, with the appropriate chemical or surgical sacrament, this separation can literally be carried out.

Yet these are precisely the "miracles" we are taught to believe in, and the idolatries to which we aspire. We prefer to forget the older and simpler truths, that the propensity or susceptibility to illness is deeply rooted in our biological nature, and that the phenomena of disease are the expression of our own life energy, trying to overcome whatever it is trying to overcome, trying, in short, to *heal* itself.

The myth that we can find technical solutions for all human ailments seems attractive at first, precisely because it by-passes the problem of healing, which is a genuine miracle in the sense that it can always *fail* to occur. We are all genuinely at risk of illness and death at every moment; no amount of technology can change that. Yet the mission of technical medicine is precisely to try to change that: to stand at all times in the front lines against disease, and to attack and destroy it whenever and wherever it shows itself.

That is why, with all due respect, I cannot have faith in the miracles or accept the sacraments of Merck, Sharp, and Dohme and the Center for Disease Control. I prefer to stay with the miracle of life itself, which has given us illness and disease, but also the arts of medicine and healing, through which we can acknowledge and experience our pain and our vulnerability, and sometimes, with the grace of God and the help of our fellow men, an awareness of health and well-being that transcends all boundaries. That is *my* religion; and, while I would willingly share it, I would not *force* it on anyone.

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Copied from Journal of the A.I.H. 76: 101, Sept. 1983.

POSTSCRIPT ON IMMUNIZATIONS:
Directions for Future Research
Richard Moskowitz, M.D.

When I wrote "The Case Against Immunizations," my intention was simply to understand my own experience, to develop a coherent and plausible line of reasoning that could explain what I had read and felt and thought about, and what my patients were telling me.

The next step is to address the issue of *experimental verification*, to try to sketch out where and how we might look for valid, repeatable evidence for the efficacy, safety, and mode of action of the common vaccines.

As I reread the argument, I realized that even the more speculative ideas in it could in fact be tested quite easily with the standard research techniques now in common use. Because I myself have very little research training or experience, I am doubly curious why such tests were not carried out long ago.

A number of scholars have certainly *entertained* these ideas before, as I indicated in the text, and even considered them publicly. The only obstacle that I can see to taking them seriously is that they are "heretical," that it would be impossible even to take the time to study them without a "paradigm shift" of some magnitude (1).

1. How Effective Are the Vaccines?

I argued in the text that if the vaccines act by *suppressing* the ability of the organism to mount an effective acute inflammatory response, then we can no longer accept a simple drop in the incidence of the acute disease as a measure of true *immunity*. I also argued that the mere presence of circulating antibody cannot suffice either, because the diseases in question do continue to break out even in serologically highly 'immune' populations.

What strikes me as a far more interesting and relevant measurement is the degree to which the vaccine "protects" against the acute disease when the latter actually does break out. This could be determined relatively easily by studying the incidence and morbidity of each disease in fully and partly-immunized populations, as compared with those of their non-immunized neighbors. Such a study would still have nothing to say about the possibility of immuno-suppression. But it would at least give a truer perspective on the ability of the vaccines to do what their proponents seem to *want* them to do.

I cannot resist pointing out that such research obviously requires a sizeable cohort of un-immunized people, which is now being provided by those parents who have refused to immunize their children, despite the concerted efforts of the medical and public health authorities to intimidate and punish them. The same result could of course be achieved much more efficiently by simply making the vaccines *optional*, as they are in West Germany, Sweden, the United Kingdom, and some other places, which would allow the experimental and control groups to select themselves. Our frantic efforts to secure 100 percent compliance with the present mandatory program evidently succeed only in making such studies impossible.

A closely-related type of study would be to measure the effectiveness of *re-immunization* at varying intervals after the original course. In this case, there would be *two* control groups:

1) the same un-immunized cohort, as before; and
2) a group of children previously vaccinated, whose parents decided not to give them the "booster" dose.

This study would also measure the incidence and morbidity of the acute disease when it *does* break out, rather than simply the circulating antibody titer, which is probably far less relevant.

My conjecture, based on the preliminary studies I cited in the text, is that both primary and booster vaccinations tend to give considerably less protection against the corresponding acute disease when it does break out than the simple drop in incidence, or the rise in antibody titer, would indicate.

Both of these studies could also be carried out in suitable animal populations, using vaccines developed against diseases peculiar to each species, such as canine distemper, leptospirosis, and the like, inasmuch as what we are concerned with includes the effectiveness and mode of action of the vaccines in general.

A third possibility would be to investigate the relationship between circulating antibody and "immunity" in the above sense. This could be done by measuring antibody titer periodically in a large pooled sample, and then retrospectively comparing baseline titers in an immunized group that subsequently developed the disease with another immunized group that was exposed to the disease but did not develop it. Both could then be compared with the corresponding non-immunized groups, who would be expected to show no measurable titers at all prior to exposure.

2. How Do the Vaccines Act?

As I argued in the text, the problem with all of these studies is that they systematically ignore the crucial possibility that the vaccines may act immunosuppressively, and may therefore produce or at least promote a variety of obscure chronic diseases over long periods of time. This is why the "effectiveness" of the vaccines cannot really be studied in isolation without first understanding their mode of action in a more comprehensive fashion.

Indeed, the issue of effectiveness is actually misleading, insofar as it leads us to focus on the typical acute disease, rather than the broad spectrum of biological effects that can be associated with bacteria, viruses, and the vaccines derived from them, a spectrum that includes latent, subclinical, and chronic phenomena as well. We certainly know of situations in which *inability* to develop acute disease represents the exact opposite of good health, i.e., the consequences of chronic immune *tolerance* rather than true immunity.

At the crudest level, then, we need to study the effects of the vaccines, both acutely and long-term, on various clinical and laboratory parameters of health and disease. In the case of the pertussis vaccine, for example, we need good prospective studies on the incidence and severity of various hematological and CNS abnormalities over time, following the administration of the single vaccine at the usual time (and at routine intervals before and after). This could be done simply and inexpensively by performing CBC's, brief neurological exams, and behavioral assessments on the same self-selected groups of immunized and un-immunized children.

Another method would be to follow certain obvious *clinical* variables at the time of the normal well-child and other pediatric visits, such as the incidence and severity of acute and recurrent URI, tonsillitis, pharyngitis, otitis media, cervical adenopathy, and the like, in both immunized and un-immunized children over a period of years.

The same experimental format should also make it possible to sort out the various patterns of chronic morbidity following each individual vaccine. Again, the crucial importance of the un-immunized cohort becomes obvious. With regard to pertussis, for example, my clinical experience to date strongly suggests that the immunized group will have a significantly higher incidence and morbidity from chronic and recurrent infections, with higher rates of complications and disability, such as myringotomies, hearing loss, etc.

A long-term study could then follow these same children through older childhood and adolescence, to determine the incidence and morbidity of various chronic diseases, such as eczema, asthma, rheumatoid arthritis, SLE, ulcerative colitis, multiple sclerosis, and other idiopathic degenerative, CNS, or connective-tissue diseases, as well as mental retardation, hyperactivity, school and behavior problems, convulsive disorders, leukemia, and other forms of cancer. Once again, my suspicion is that the immunized group would show a significantly higher increase in the incidence and morbidity in all these categories. I *hope* I'm wrong, but I don't think I am.

Another interesting and useful study would be to measure the effect of the common vaccines on the incidence and morbidity of other acute infections to which the individual was definitely or probably exposed (influenza, hepatitis, genital herpes, Colorado tick fever, etc.). The point here would be to see if the vaccination process has any effect on the capacity of the immune system to deal with acute infection generally, which seems quite probable.

In this case there would be two control groups:

1) one group of children not previously immunized (against measles, mumps, or whatever), who were subsequently exposed to influenza, hepatitis, or some other acute infection; and
2) a group of similar children who contracted and recovered from acute measles, mumps, or whatever, some time before their exposure to influenza, hepatitis, etc.

Again, my conjecture is that both groups, while perhaps no less likely to *contract* the second disease, would show significantly less acute and chronic *morbidity* as a result of it.

Along these same lines, it would not be very difficult to design some good animal studies investigating the possibility of immunosuppression by the vaccines. This could be done by measuring leukocyte and macrophage activity both *in vivo* and *in vitro*, in response to various challenges, such as exposure to unrelated infections, allergens, and chemicals. Various liver-function tests, as well as the ability of the spleen and bone marrow to respond to hemorrhage and blood transfusion could also be followed. Finally, the ability of both immunized and un-immunized animals to reject homografts could be measured quite easily.

Careful cytogenetic studies could also be made, to show the effects of vaccination on karyotype and chromosome morphology, beginning with typical "target" cells for which the vaccine in question has a known affinity (e.g., liver parenchymal cells in hepatitis, parotid acinar cells in mumps, cells of the nasal mucosa in measles). Careful virological studies of these same cells should also make it possible to recover or at least demonstrate the existence of episomes or viral nucleoprotein moieties within the DNA or RNA of the host, which would confirm the suspicion of latency and chronic infection, at least in the case of the live vaccine.

But, whichever studies are done, the point is that the technology to do them already exists; and the only thing that prevents them from being done is our own ideological resistance to the self-evident truth that vaccines are not simply "wonder drugs" that produce specific antibodies and nothing more, but complex, biologically-active substances whose effects on the human organism urgently need to be investigated.

NOTES.

1. Kuhn, T.S., "The Structure of Scientific Revolutions," University of Chicago, 2nd Edition, 1970, Chapters 1 and 2.

Dissatisfied Parents Together News
Box 563, 1377 K St. N.W., Washington D.C., 20005

11/27/83

Dear Dr. Morris—

Enclosed is a copy of S. 2117, the National Childhood Vaccine-Injury Compensation Act, introduced 11/17/83 by Senators Hawkins & Hatch. We would very much appreciate your review and suggestions regarding the bill. Although it has been introduced, it is surely not locked in stone and we would welcome your suggestions for how the bill could be improved.

From our standpoint in negotiating with the AAP, we do not feel the bill is "perfect". In fact, there are numerous things that we would probably change. But some constraints of political feasibility were operative and we did the best we could at this stage in the process.

Hopefully with your suggestions the bill can be improved.

With appreciation for your assistance in the past and longstanding commitment to the health of our children.

Sincerely,

Jeff Schwartz

THE BELL OF ATRI, Inc.

7 January 1984

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Mr. Jeff Schwartz, Esq.
Box 563
1377 "K" Street, N.W.
Washington, D.C. 20005

Dear Mr. Schwartz:

At a meeting at the National Institutes of Health in Bethesda several months ago, lawyers instructed physicians and other government employees, who deal in their official capacity with the public in matters of health, on how to conduct themselves and on how to keep records to maximize protection against losing in the event that a member of either group is sued.

In your 27 November note (concerned with S. 2117, the "National Childhood Vaccine-Injury Compensation") you wrote that "We would very much appreciate your review and suggestions regarding the bill . . . From our standpoint in negotiating with the AAP [American Academy of Pediatrics], we do not feel the bill is 'perfect' . . . There are numerous things that we would probably change. But some constraints of political feasibility were operative and we did the best we could at this stage in the process."

In an attachment [Congressional Record--Senate, November 17, 1983] to your 27 November note, Senator Hawkins wrote, in part (page 16612):

> Increased vaccine costs threaten the childhood immunization program in another way: Dramatic increases in price mean that fewer children will be immunized. According to a spokesperson of one of the three private pharmaceutical companies currently manufacturing the pertussis vaccine, the cost of a 15-dose vial of pertussis vaccine increased from $4.67 to $42 in June of this year. That represents an unbelievable tenfold increase. The company had only two alternatives: either to discontinue manufacturing the vaccine or to increase its price radically. The director of marketing of that U.S. vaccine manufacturer, Douglas Reynolds of Connaught Laboratories, informed the chairman of the Academy of Pediatrics's Committee on Infectious Diseases

that "Connaught definitely endorses the concept of new legislation to establish a compensation system for those individuals who suffer a serious adverse reaction and attendant losses as a result of vaccination. Such a system should: One, assure that those actually injured are compensated for their losses to the extent society can reasonably provide, and two, eliminate the frivolous lawsuits that even when thwarted have substantial costs involve. Neither the vaccine manufacturers nor other responsible parties in the medical community are looking for an escape from the costs of negligence, but the concept of absolute liability applied to immunization is not in the best interest of society's public health goals."

With the information contained in the above paragraphs in mind, we followed your suggestion and reviewed S. 2117. Some comments resulting from our review follow:

Sec. 2111(d)

(3) nothing included (or referred to) in the Vaccine-Injury Table in section 2114(a), nor excluded from such table, shall be admissible for any purpose whatsoever in any action in tort in any State or Federal court for damages for any vaccine-related injury. Nor shall any matter included in, referred to, or excluded from, such table be afforded any weight by the decider of fact in any such action in tort.

(4) nothing included (or referred to) in the review list in section 2114(c), nor excluded from such list, shall be admissible for any purpose whatsoever in any action in tort in any State or Federal court for damages for any vaccine-related injury . . . (underscorings here and elsewhere in this letter are ours).

Comment:

While the words in the above sections might make legal sense, in our judgment, they violate common sense, since "nothing . . . in the . . . table . . . nor excluded from [the table] shall be admissible . . ." means that nothing in the universe remains to be admissible since all in the universe is either in or out of the table. The same applies to the review list.

Sec. 2112(a)

(3) the first symptom or manifestation of the onset (or significant aggravation) of any such illness, disability, injury or condition occurred within the requisite time period after vaccine administration set forth in the Vaccine-Injury Table under section 2114, regardless of whether or not such symptom or manifestation was recognized or recorded as such within that period

Comment:

Even a casual examination of the relevant medical literature will show that a significant number of cases of vaccine induced "illnesses, disabilities, injuries or conditions listed in the Vaccine-Injury Table under section 2114" occurred later than "the requisite time period after vaccine administration set forth in the Vaccine-Injury Table under section 2114." These cases (with delayed onset of symptoms and manifestations of vaccine induced damage) are excluded from relief under provisions of S. 2117.

Sec. 2113(f)

(1) A decision to provide compensation under this title, when final, shall constitute an obligation of the United States and shall be backed by the full faith and credit of the United States.
(2) Compensation shall be paid from the National Vaccine-Injury Compensation Trust Fund established by section 2119.

Sec. 2119(c)

(2) The surcharge(s) shall be established by the Secretary of Health and Human Services on each childhood vaccine listed in the Vaccine Injury Table under section 2114, for each manufacturer of such product sold in the United States, after consultation with the Commission established under section 2118, on July 1, 1984, and on July 1 of each succeeding year.

Comment:

Senator Hawkins wrote in her statement published in the Congressional Record (17 November 1983, page 16612, and quoted at length in paragraph 3 of this letter):

> Increased vaccine costs threaten the childhood immunization program in another way: Dramatic increases in price mean that fewer children will be immunized. According to a spokesperson of one of the three private pharmaceutical companies currently manufacturing the pertussis

vaccine, the cost of a 15-dose vial of pertussis vaccine increased from $4.67 to $42 in June of this year. That represents an unbelievable tenfold increase. The company had only two alternatives: either to discontinue manufacturing the vaccine or to increase its price radically.

There is nothing in S. 2117 that precedes or follows Sec. 2119 that shows that establishment of a "uniform or variable annual surcharge on the manufacturer of each vaccine listed in the table in section 2114" will not result in further increases in vaccine costs--cost increases that even now are characterized by Senator Hawkins as "dramatic" and that ". . . mean that fewer children will be immunized."

Sec. 2114(b)

(6) (C) In assessing whether a petitioner has suffered a chronic or long-term complication or sequela of an encephalopathy (acute) under this title, the court shall consider, in addition to other appropriate factors, whether and, if so, when and to what extent the petitioner has suffered the following effects: seizures, convulsions, or focal neurological signs; developmental delay, learning disabilities, or mental retardation; hyperkinesis; paralysis or other motor or muscular impairments; sensory impairment or loss; unusual or extreme emotional dysfunction.

Comment:

What is an unusual or extreme emotional dysfunction? The answer depends upon the observer and the reporter of the dysfunction. This is a kind of loophole through which many escape-leaps have been made in the past and through which many more escape-leaps will be made in the future.

Sec. 2114(c)

(1) Not later than three years after the date of enactment of this title, the Secretary shall complete a review of all relevant medical and scientific information (including information obtained from the studies required under paragraph (6)) on the nature, circumstances, and extent of the relationship, if any, between pertussis-containing vaccines (including whole cell, extracts, and specific antigens) and the following illnesses or conditions:
(A) hemolytic anemia . . .

Comment:

We believe that a worthwhile evaluation of a recent review involving the Secretary [of the Department of Health and Human Services] can be derived from your words given at the Open Meeting, Pertussis and Pertussis Vaccines, Interagency Group to Monitor Vaccine Development, Production and Usage, Rockville, Maryland, 26 April 1983. Before that group, you began your statement with "We are given ten minutes to present a point of view on a subject that is so complex, that ten minutes cannot begin to do justice to it" and near the close of your statement with "We think the whole notion of causation that has been applied to the SIDS analysis would never survive scrutiny if it were applied to any other situation. It would never--you would never apply the same test of causation to cigarette smoking or air pollution control . . . and yet you have been willing to go back and make your best effort to find out what the reactions are there and to find out what the risk factors are and to not require proof beyond any possible doubt." (For your convenience, a copy of the full text of your statement and comments are attached to this letter.)

So much for the quality of reviews that "the Secretary shall complete . . ."

Sec. 2114(c)

(6) (D) There are authorized to be appropriated such sums as are necessary for fiscal years 1984, 1985, and 1986 for the purpose of making payments for the conduct of the studies required under this paragraph. If appropriations under this subparagraph are insufficient for making such payments, then payments shall be made from the trust fund established under section 2119.

Comment:

What assurances are given in S. 2117 that expenses incurred in "the conduct of the studies required under this paragraph" will not bleed to exhaustion "the trust fund established under section 2119"?

Sec. 2117(a)

(2) (c) Any Federal district court referred to in subsection (b) shall have jurisdiction to entertain such civil action, to award appropriate damages as provided in subsection (a) to the Fund, and to enforce its orders and decrees, in any case in which the Secretary proves by a preponderance of the evidence that the compensated party's injuries were proximately caused by the defendant's negligence or by a vaccine which was defective or unreasonably dangerous.

Comment:

What is an unreasonably dangerous vaccine?

A careful review of the first thirty-three pages and a brief scan of the remaining twenty-one pages [we will not make comments, many as there are, resulting from the scan of the twenty-one pages for if we did this letter would go on and on] of S. 2117 ("National Childhood Vaccine-Injury Compensation Act") resulted in the following conclusions:

1. Physicians and other health care providers as well as vaccine manufacturers, acquainted with the kind of legal advice given at a meeting at the National Institutes of Health several months ago to physicians and other government employees who deal in matters of public health, will use the provisions of S. 2117 to their advantage while children who suffer serious adverse reactions to administration of childhood vaccines will be grievously disadvantaged by the provisions of this bill.

2. We agree with you that the bill is not "perfect," but we go further: passage of S. 2117 into law might be acceptable in Utopia, but passage of S. 2117 into law will be catastrophic in the real world. Our reasons for this conclusion are given in our comments on this carelessly drawn bill in earlier paragraphs in this letter and in your observation that ". . . some constraints of political feasibility were operative and we did the best we could at this stage in the process." Our agreement with you that the bill is not "perfect" is reinforced by these words from Senator Hawkins' statement: "The director of marketing of that U.S. vaccine manufacturer, Douglas Reynolds of Connaught Laboratories, informed the chairman of the Academy of Pediatrics's Committee on Infectious Diseases that 'Connaught definitely endorses the concept of new legislation to establish a compensation system for those individuals who suffer a serious adverse reaction and attendant losses as a result of vaccination. Such a system should . . . assure that those actually injured are compensated for their losses to the extent society can reasonably provide . . .'"

We undertook review of S. 2117, at your invitation, with the background given in paragraph 4 of this letter and with knowledge that we do not operate under "constraints of political feasibility" and we now suggest that if the provisions of this bill become law, it will be a great day for the American Academy of Pediatrics and for Connaught and for other vaccine manufacturers but a sad day for the children of this country.

I hope that you accept our comments and conclusions drawn from our review of S. 2117 in the spirit of helpfulness and cooperation with which they are sent.

Very best for a good New Year.

Sincerely,

J. Anthony Morris

J. Anthony Morris, Ph.D.

John Chriss Hoffman

John Chriss Hoffman, M.J.

cc: Senator Paula Hawkins

Jo Ann Cook
P.O. Box 5511
Pine Bluff Ark. 71611

Paula Hawkins
United States Senator

Dear Senator Hawkins

I am encouraged by your letter dated April 10, 1984 stating that the parents panel has been expanded to include additional persons as *well* as submitted testimony.

I wish to submit written testimony in S-2117 and the compensation program as follows:

On the face of Senate Bill S-2117 the purpore appears to be to compensate those children with sustained and uncorrectable damage.

In further investigation of the Bill content it is apparent the purpose is not to compensate children but to decrease the liability of those with vested interest, i.e., the manufacturer's of vaccinations, Medical Doctor's and Public Health Bodies. Yet it is these same persons that have failed the children by not improving the defective immunization programs. To legislate a Bill of compensation for children will encourage these bodies to continue defective practices.

The Courts have held that the legislative body of each State has the police power to enact law concerning immunization. I would conclude from this that a responsible compensation would be accomplished by the same body that enabled the damage.

The compensation Bill S-2117 as now written will be compensation for a loss of quality of life. No one should have to show 85% damage for comensation when any damage is loss of quality of life. I have personaly paid medical bills of $300.00 a month for periods following immunization. I was told by Pediatricians that reactions to the vaccination could be reversed but in fact all that can be done is to treat the symptions. I have one child with asthma, one child with allergies to food, medicines, and house use products. I was not informed that a suspected carcinogenic (Formaldehyde) was contained in the DPT vaccine. It would be an injustice to citizens to ask that they face the burden of damage for defective vaccines.

If the Bill S-2117 passes as it now stands it will deny children of equal, protection and establish unreasonable time periods for adverse reactions to manifest. For a compensation Bill to be of any value it would have to be automatic with minimum amount of burden not a court battleground. To be effective to reduce damage it would have to include provisions for the informed parent to decline the immunizations.

Sincerely

Jo Ann Cook

Senator HAWKINS. That will conclude this hearing. Thank you all for helping.

[Whereupon, at 1:15 p.m., the committee recessed, subject to the call of the Chair.]

○